

**Influence of digital design and fabrication of  
surgical guides on the accuracy of implant placement  
- A doctoral thesis**



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## Table of contents

<b>Abbreviations and definitions</b> .....	3
<b>List of papers</b> .....	4
<b>Abstract</b> .....	5
<b>Introduction</b> .....	8
Is there a need for computer-guided implant surgery .....	8
Osseointegrated dental implants .....	10
Analog implant installation procedure .....	13
Digital advancements in the implant planning and installation procedure .....	15
Integration of an intraoral surface scan .....	19
Fusion of data from CBCT and intraoral scanning .....	20
Different types of guided implant surgery .....	21
Dynamic guided implant surgery .....	21
Template guided implant surgery – static .....	22
Bone supported guides .....	23
Mucosal supported guides .....	24
Tooth supported guides .....	24
Planning procedures – guided implant surgery .....	26
Surgical guide production .....	27
Manual production .....	27
Digital additive manufacturing .....	29
Clinical application of surgical templates .....	30
Learning curve .....	31
Implant survival .....	31
Mispositioning of the surgical guide .....	33
Assessment of deviations between planned and achieved implant positions .....	33
Clinical outcome of guided implant surgery .....	36
<b>Aim</b> .....	37
<b>Hypothesis</b> .....	38
<b>Materials and methods</b> .....	39
Experimental considerations .....	39
Procedures .....	40
<b>Results</b> .....	52
<b>Discussion</b> .....	55
Introduction .....	55
Case preparation for the digital planning procedure .....	56
CBCT acquisition, segmentation, and superimposition .....	59
The guided implant software .....	61
The ideal implant position .....	63
Surgical guide design .....	65
Surgical guide production .....	66
Execution of template guided implant surgery .....	69
Evaluation procedures .....	72
Consequential errors .....	73
Patient benefit from guided implant surgery .....	73
Limitations .....	74
Achieved results .....	75
<b>Concluding remarks</b> .....	78
<b>References</b> .....	79



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## **Abbreviations and definitions**

**2D:** Two dimensional

**3D:** Three dimensional

**Angular deviation:** The angular deviation is calculated as the angle between the longitudinal axis of the planned and placed implant.

**Apex:** Tip of implant

**ASA:** American Society of Anesthesiology

**CAD:** Computer-aided design

**CAM:** Computer-aided manufacturing

**CBCT:** Cone beam computer tomography

**Depth:** Depth deviation is calculated as the distance between the coronal (or apical) center of the planned implant and the the intersection point of the longitudinal axis of the planned implant with a plane parallel to the reference plane and through the coronal (or apical) center of the placed implant.

**DICOM:** Digital imaging and communications in medicine

**IO scanning:** Intraoral scanning

**Global deviation:** Global deviation is defined as the 3D distance between the coronal (or apical) centers of the corresponding planned and placed implants.

**Gymm<sup>2</sup>:** Gray per square millimeter. Relates to the absorbed dose.

**Hounsfield scale:** Quantitative scale describing radiodensity

**KV:** Kilo Volt

**Lateral deviation:** Lateral deviation, a plane perpendicular to the longitudinal axis of the planned implant and through its coronal





## List of papers

No. 1

**Comparison of postoperative intraoral scan versus cone beam computerised tomography to measure accuracy of guided implant placement—A prospective clinical study.**

Skjerven H, Olsen-Bergem H, Rønold HJ, Riis UH, Ellingsen JE.  
Clinical Oral Implants Research 2019; 00:1–11.

No. 2

**Evaluation of the accuracy of implant placement using stereolithographic guides**

Skjerven H, Brokstad Herlofson B, Wohlfahrt JC, Ellingsen JE  
Manuscript

No. 3

**In Vivo Accuracy of Implant Placement Using a Full Digital Planning Modality and Stereolithographic Guides**

Skjerven H, Riis UH, Herlofsson BB, Ellingsen JE  
Journal of Oral and Maxillofacial Implants  
Volume 34, Issue 1, January/February 2019, Pages 124–132



## **Abstract**

### **Aim**

The aim of the present thesis was to study whether digital design and fabrication of surgical guides can improve the accuracy of implant placement.

### **Hypothesis:**

The null hypothesis ( $H_0$ ) is that the introduction of digital tools, to reduce the number of manual procedures in guided implant surgery, do not reduce the observed variations between planned and achieved implant positions.

### **Methods:**

The null hypothesis was tested in three experiments where different guided implant surgery software were applied in a clinical setting.

Manual labor processes were a significant part of study No 1. The desired prosthetic reconstruction was built in wax by a dental technician and converted into a surgical template after CBCT acquisition and surgical planning using a mechanical device. The desired prosthetic reconstructions were designed in a computer based on a digitized plaster cast in study No.2. The digital plaster cast were superimposed onto the volume rendered 3D model generated from the CBCT and the surgical planning was performed by the restorative team. The surgical template was designed in the software and printed in a stereolithographic process.

All procedures were digitized in study No 3. The planning procedures were performed by the restorative team based on an intraoral scan superimposed onto the volume rendered 3D model generated from the CBCT. The surgical template was designed in the software and printed in a stereolithographic process.

All included implants were put in one group and four common parameters were measured: The position of the implant collar and apex, the depth of the implant and the angle of their long axis. The primary outcome variables were measured as differences between the planned and achieved implant positions.

## **Results**

The common metric measurements in the three studies were extracted from metrology software and analyzed in STATA v.14. The depth, angle and global deviations at the apical point revealed significant median differences between the three studies. All differences were considered significant at  $p < 0.05$ . The metric deviations between the planned and achieved implant positions increased with the introduction of digital procedures. Study No 1 showed that it is possible to plan and place implants with a high degree of accuracy based on a mainly manual procedure. Study No 2 and 3 resulted in an increasing discrepancy between the planned and achieved implant positions as more digital procedures were introduced. The statistically most significant difference between study No 1 and the two latter studies were in the vertical direction.

## **Discussion**

The included studies in this thesis apply three different guided implant surgery software and differ in the planning procedures necessary to perform the treatment. The studies yielded metric deviations in line with other clinical studies on guided implant surgery, and all had a high degree of accuracy regardless of the manual procedures involved. Replacement of manual processes gave a significant negative effect on accuracy parameters.

Median depth measurements for studies 2 and 3 reveal that the implants are placed higher than planned. The interquartile range for the global deviations is rather low. This will indicate that the surgical guides are not placed in the correct position in the patient's mouth – but are placed too high compared to the digital plan.

The results indicate that there is a relative difference in the surgical guide position in the implant planning software and the patient. The conclusion should be interpreted with care as there are limitations related to the number of patients included, statistics, different stereolithographic printers, metrology software and CBCT machines.

## **Conclusion**

The measurements extracted from the three studies included in this thesis support the null hypothesis.

The significant difference in median depth deviations between studies indicate that the deviations associated with the stereolithographic production of the surgical guides are the most prominent.

## **Introduction**

### **Is there a need for computer guided implant surgery?**

Healthcare innovation is driven by technology advancements to improve personalization, quality, and patient safety. Many areas in medicine experience the introduction of digital technology and dentistry is no exemption. Technological advancements have changed how dentists diagnose and treat patients. Computer systems are now able to visualize human anatomy as well as planned treatments to increase the quality of the planning ahead of treatment. Different systems have been developed to optimize the performance in human working procedures necessary to deliver the treatments results our patients expect. New and simplified digital workflows are introduced to help clinicians work more efficiently and with higher precision covering all aspects from diagnostics to planning and execution.

Surgical treatment with dental implants is such a complicated clinical procedure where even small deviations between the planned and achieved implant positions may affect the result. Guided implant surgery is a procedure developed to assist the human operator in the transfer of a virtual plan to the patient. There are certain situations where guided implant surgery seems to offer a valuable contribution to treatment with dental implants.

1- Guided implant surgery following a three-dimensional implant planning with assessment of the available bone volume and positioning of vital structures such as blood vessels, nerves and other teeth, may result in increased patient safety (1, 2).

2- Minimal invasive surgery made possible using guided implant surgical procedures may be an advantage for patients who would benefit because of certain medical conditions – or the desire for minimal postoperative problems (3-6). Flapless or mini flap implant installation procedures may reduce morbidity related to hemorrhage and postoperative symptoms.

3- The use of surgical guides facilitates optimization of implant positions in critical esthetical cases or full arch bridges (7).

4- Computer guided implant surgery opens the possibility to provide a temporary restoration at the time of surgery. This may exclude the need for a temporary removable prosthesis which some people experience affects their oral function and social interactions.

Younes and co-workers compared the effectiveness of free-handed surgery and guided implant surgery. They concluded that guided surgery was more effective regarding accuracy. Time investment were comparable between the groups and their opinion was that guided implant surgery was an acceptable treatment modality and clinically justified as cementation of the prosthetic reconstruction could be avoided (8). Screw retained implant restorations are favorable as they are possible to disassemble from the implants when hygiene maintenance, repairs or surgical interventions are required to extend the life cycle of the implant restoration. Cement remnants are common on abutment surfaces in cases where the prosthetic restoration is luted and may contribute to development of peri-implantitis (9). Achieving a screw retained

reconstruction may as well contribute to the management of esthetic complications (10). Studies have pointed out the importance of facilitating maintenance and repair of implant based restorations (11).

Teeth and mucosal supported guided surgery have the opportunity for flapless surgery that has the advantage of reduction in postoperative discomfort (6). The positive patient centered outcomes associated with flapless surgery are reduced swelling, oedema, hematoma, hemorrhage, and trismus (12, 13).

An interesting aspect associated with the flapless procedures are the possibility to treat medically compromised patients. Horowitz and co-workers used guided implant surgery on irradiated cancer patients with good results after two years (14).

An increase in the use of guided implant surgery should be expected as the patients demand increased safety and a more predictable outcome of the treatment procedures. The increased cost related to the application of guided implant surgery needs to be justified for the patient (8) in each case providing a significant advantage seen from the patient perspective.

### **Osseointegrated dental implants**

Oral rehabilitation using osseointegrated dental implants was introduced in clinical dentistry more than 50 years ago (15-17). Clinical procedures have developed significantly since Pär-Ingvar Brånemark demonstrated the formation of bone at the titanium implant surface in the early nineteen seventies (18, 19).



The Brånemark group demonstrated a successful application of dental implants in the treatment of edentulous patients (19, 20) and the concept has further evolved into a routine therapy for the rehabilitation of partial and fully edentulous patients (15, 21).

The clinical procedures for treatment with use of dental implants have changed during the last decades. New technologies have been applied to increase patient safety, quality of the planning and execution of the procedures as well as patient outcomes. Clinical procedures in dental implantology have evolved from manual inspection of the oral tissues combined with conventional 2D x-rays to a digital procedure where patients anatomy is described in a digital environment based on 3D x-rays and digital surface scanning.

As technology is evolving manual procedures are to an increasing extent replaced by digital counterparts (22).

The conception of an ideal treatment result has changed among the public. Patients demand for restorations of high esthetics have had a major impact on the development of procedures, component design and materials used in dental implantology (23).

The materials and components have correspondingly been refined to a level where it is possible to make long lasting, esthetically successful and hygienic dental restorations (24).

The traditional implant treatment planning procedure based on a clinical examination, 2D x-rays and “mental” surgical execution has been challenged by a three-dimensional data collection where the restorative team can collaborate, plan treatments in detail and execute based on the assembled data and digital aids (25).

The introduction of technologies such as CBCT, IO scanning and CAD / CAM manufacturing have contributed to more predictable treatment outcomes and made them more accessible to clinicians (7).

The increased use of advanced tomographic equipment and expensive planning tools must be justified to the public. The higher ionic load as well as increased cost must be reflected by advantages experienced from the patient perspective – not only alleged advantages reported from dentists. Recent treatment possibilities such as immediate loading of implants with temporary restorations and minimal invasive surgical techniques may open for an increased acceptance from the public.

The new treatment possibilities offer more advantages seen from the professional perspective. The optimized planning procedure brings the prosthetic perspective closer into the surgical planning: The “crown-down” planning principle aims to achieve a more ideal implant position related to the desired prosthetic restoration. There are positive benefits from an ideal implant position as patient’s hygiene measures are more convenient because of the possibility for ideal abutment design, the biomechanical loads are distributed more ideally, and it is possible to manufacture an esthetical pleasing restoration.

Application of guided implant surgery may offer possibilities to rationalize the planning procedures for dental implant treatment where procedures traditionally performed by dental technicians may be replaced by digital equivalent procedures in the dental office. Common processes such as conventional plaster cast manufacturing and manual wax up of planned prosthetic restorations are now possible to achieve by intraoral scanning, computer assisted design software (CAD) and 3D printers. The resulting files may in guided implant surgery planning be projected onto the tomographic volume to visualize the relation between the anatomy, planned prosthetic restorations and implants. The digital planning procedure has significant advantages for the restorative team as a common platform for collaboration.

Manual manufacturing of surgical templates has been replaced by computer assisted manufactured (CAM) templates as technological improvements have introduced digital manufacturing, (26-28) a process that may as well take place in the dental office (29).

### **Analog implant installation procedure**

The surgical procedure needed for installation of dental implants requires experience and clinical skills (30). The implants must be placed in an optimal position related to the available bone as well as the prosthetic restoration to be able to manufacture screw-retained, hygienic, and esthetically pleasing reconstructions. The analog implant installation is a freehand procedure.

A combination of 2-dimensional (2D) x-rays and a clinical examination has traditionally been the main tools used by the clinician to decide the implant size and position ahead of the surgical installation of the dental implant. Conventional 2D radiographs provide sufficient information on height and mesio-distal width of the alveolar bone, but limited information on the bucco-lingual width. Radiographic artefacts, distortion and in some cases, lack of sharpness may as well compromise the exact description of the surgical area and may yield misleading information (31). Surgical stents are used to indicate the tooth positions as well as the inclination of the planned teeth related to the jawbone. The surgical stent is a device which the clinician can place onto the surgical site indicating the position and inclination of the planned prosthetic restoration. Different versions of surgical stents have been applied in dental implantology for many years (32) to aid the surgeon in placing the implant in the correct position in relation to the prosthetic reconstruction.

Preston's acrylic resin splint concept was introduced as an instrument to verify the aesthetic form of prosthetic rehabilitation. The concept was based on a diagnostic wax up on study casts which later were converted into temporary restorations. (33). Jack D Preston developed a systematic approach where the aesthetic form of the prosthetic restorations was established in advance of the treatment and used as a guide for further prosthetic treatment. Blustein and

co-workers described problems related to improper implant positioning and proposed that a modified Preston`s splint would improve the guiding of the implant installation (34). Blustein argued further that improper implant position could result in poor form and contour of the prosthetic restoration, tilted teeth, occlusal interferences as well as closed embrasures.

The Preston clear acrylic splint made pre-operatively by the prosthodontist was based on a pre-operative wax up of the planned restorations and gave the surgeon an indication of the desired position, angulation, and parallelism of the dental implants and an indication on the desired tooth form, size, and position.

In the early days of oral implantology most patients treated were edentulous and the surgeons focus was to secure a solid position for the implant embedded in sufficient bone. The positions were thus determined by the volume and quality of the residual bone and the angulation of the implant was determined by the position of the crest and the remaining teeth in the opposite jaw(35). The decisive parameters for implant positioning could lead to unfavorable positions, yielding prosthetic reconstructions suboptimal esthetics and a more difficult hygiene procedure. The present situation, where most dental implants are placed as replacements of single teeth, have the same problems associated with suboptimal implant positions. The increased focus on esthetics, hygiene maintenance and patient safety has increased the attention to the problems associated with the manual, free hand, implant installation procedure. New implant installation procedures have been implemented based on technological advancements in computers, x-ray modalities and digital intraoral surface scanning.

## **Digital advancements in the implant planning and installation procedure**

There were few alternatives to the conventional dental implant planning and installation procedures until technological advances in other medical fields were introduced in the nineteen nineties. Sir Godfrey N Hounsfield shared the 1979 Nobel prize in medicine with Allan M Cormack after developing a method to acquire radiographs from different directions and angles, and digitally processing these to a three-dimensional depiction (36). The first scanner, known as the EMI scanner, used several hours to acquire the raw data, and several days to reproduce the images. Later advancements in computing power and resolution in the acquisition detectors have increased image processing speed and quality. The data acquired from a computer tomograph is a volume of voxels. The voxel consists of pixels and are described by the computer as a value in a three-dimensional space and presented to the viewer as slices in different planes as well as a volume rendering where the 2D data is presented as a 3-dimensional model. This is possible as the pixels are acquired and displayed with their radiodensity according to the attenuation of the tissues described. The attenuation is described on the Hounsfield scale from +3.071 (most attenuating) to -1.024 (least attenuating). Computer programs were developed in the late 1980's to visualize the human head using the computerized tomography images developed by Hounsfield and Cormack. The images were used to guide surgical instruments to points of interest during head (brain) surgery. The "Viewing wand" were a unit developed for neurosurgery as an adjunct to computerized tomography (37). The system was the breakthrough for guided surgery as it combined virtual reality and conventional surgical procedures. The primary benefit of the innovative procedure was an increased patient safety due to the possibility for visual navigation of the instruments during surgery. The algorithms processing the tomographic images took several hours to develop a single image in the 1980's. Developments in computer processors, RAM memory speeds and algorithms have accelerated image processing and lowered radiation.

The introduction of computer tomography and three-dimensional imaging tools have had a major impact on virtual dental implant treatment planning. Materialise (Materialise, Leuven Belgium), introduced in 2002 the technology for drilling holes in jawbone to an exact depth and direction through a surgical guide. The surgical guide was a device custom made for each patient and placed on jawbone, mucosa or teeth containing drilling holes guiding the implant to its planned location. The first version of Simplant software was developed already in 1993 and had the possibility to place images of dental implants with exact dimensions on cross sectional, axial and panoramic views of computerized tomography images.

The surgical guide from Materialise made it possible to perform the osteotomy drilling to an exact depth and with a predetermined direction. The technology made it possible to virtually plan the ideal implant position while considering vital anatomic structures and the desired prosthetic reconstructions and apply the plan when performing the surgery. Later improvements of the software have given the possibility to include the planned prosthetic restorations into the guided surgery software. The possibility to visualize the planned prosthetic restorations may increase the quality of the preoperative planning further as this will offer the possibility to optimize implant positions in relation to the planned prosthetic restorations. The actual 3-dimensional positioning of the implant in relation to the dental reconstruction may improve the result (34, 38, 39). Later technological advances as the cone beam computer tomographs (CBCT) and intra-oral scanning (IO scanning) technologies have had a major impact on the digital procedures and have led to the development of several new implant planning systems (40).

The foundation for the guided implant planning procedure is the acquisition of a computer tomograph. The acquisition results in an accumulation of a data volume. The tomographic volume needs to be processed before it can be used for planning purposes.

There are several computer tomographs available today and each device has specific reconstruction software allowing three-dimensional visualization of the anatomy. The tomographic data volume is sliced into 2D layers which can be viewed on the computer monitor. The images are presented in a grey scale which are based on x-ray attenuation in the voxels building up the tomographic volume. Specific structures can be separated from the volume based on a defined range of grey values (41) and may be presented to the viewer as a 3D volume rendered model. The computer tomographic data are exported in the “Digital imaging and communications in medicine” (DICOM) format. The presence of metallic fillings or crowns may cause artefacts in the volume. This may result in a masking of anatomical structures important for the planning procedure (42). The tomographic data are thereafter transferred to software especially made for dental implant surgery planning (43).

The cone beam tomographs (CBCT) became available in the first decade of the 21-century. The CBCT's have potentially lower radiation doses and high-quality cross-sectional imaging and 3D reconstructions. CBCT has generally a lower radiation dose compared to medical CT (MSCT), but there are unfortunately large differences between the available CBCT systems. (44-49).

Loubele and co-workers compared the accuracy of CBCT and MSCT for linear jawbone measurements on ex vivo specimens. Their conclusions were that both CBCT and MSCT yielded submillimeter accuracy for linear measurements (50). Abboud and co-workers compared the accuracy of MSCT and CBCT and found that the MSCT provided the most accurate images (51). They concluded, however, that the differences between the modalities were small and of negligible clinical significance. Abboud noted, however, that CBCT has problems associated with the rotation of the sensors which may lead to image distortion. This

may affect fiducial marker localization in guided implant surgery – and may have had an effect on the present studies.

Studies have shown geometric differences in accuracy between different CBCT devices from different manufacturers (52). Dreiseidler and co-workers investigated the use of three different CBCT devices in an in vitro study and compared the differences between the planned and achieved implant positions. The group found a surprisingly high difference of 0,6 angle degrees and linear deviations of about half a millimeter between the devices (53).

To minimize the inaccuracies generated from x-ray acquisition it is important to use the equipment according to the manufacturer's instructions, separate the jaws to be able to see the dental cusps clearly as well as assure that the patient stays completely still during the acquisition. Patient movement during acquisition may compromise the 3D volumetric data. Petterson and co-workers described patient movement during the acquisition as a significant factor to the final accuracy of the procedure (54) because it may affect the accuracy of the superimposition of the different CBCT volumes. Petterssons study revealed that the 3-dimensional models based on tomographic data with patient movement during the acquisition was inaccurate.

The SEDENTEXCT project released guidelines for the use of CBCT's in dental and maxillofacial radiology in 2011. The aim of these guidelines was to provide recommendations for the dentists to various clinical situations that will ensure that important diagnostic information is obtained with "As Low As Reasonably Achievable" (ALARA) radiation exposure. The European Association for Osseointegration held a consensus workshop in 2011 on the use of diagnostic 3D imaging in implant dentistry. The conference considered guided



implant surgery to be a situation where patients might benefit from cross-sectional imaging stating: “Where implant positioning can be improved so that biomechanical, functional, and aesthetic treatment results are optimized”. The diagnostic information can be enhanced by use of radiographic templates, computer assisted planning, and surgical guides (46).

### **Integration of an intraoral surface scan**

MSCT and CBCT's are not accurate in reproducing the surfaces of teeth. An accurate reproduction is important in static tooth supported guided implant surgery as the guides need a stable support to avoid movement during implant insertion. The scan prosthesis in the laboratory-based production of tooth retained surgical guides assure the adaptation to remaining teeth as the prosthesis is built on a plaster cast prior to the computer tomograph acquisition and is later converted into the surgical template. The CAD CAM (computer aided design / computer aided manufacturing) manufactured surgical guides rely on surface scanning of plaster casts or direct intraoral scanning. Digitalization of plaster casts have been described and the accuracy verified in several studies (55-58). There are several intraoral scanners (IO scanners) available on the market which can deliver reasonably accurate reproductions of intraoral surfaces (59-64). The generated scanning data are stored in a Standard Tessellation Language (.stl) file. The .stl files describe the surface geometry by vectorized points connected by polygons. Each point is described in a three-dimensional environment, a point cloud. The polygonal surfaces between the vectorized points are estimated by the computer as flat surfaces. This may limit the ability to describe acute angles and may implicate a sub-optimal description of certain aspects of teeth such as incisal points and occlusal edges.

The files may be used for a description of the surface as well as for CAD/CAM processing in a complete digital workflow (65-67). The accuracy of digital reproduction of teeth are verified in several studies to be at least as accurate as indirect digitalization (68, 69).

There are differences in accuracy for full arch scans between different IO scanners (70). The differences may reach clinically significant levels especially if the users scan strategies are sub-optimal (71-73).

Gan and co-workers investigated the accuracy of digital impressions of palatal soft tissues and found the accuracy to be satisfactory, even though there are associated deviations related to the process (74, 75). The use of intraoral scanners in the rehabilitation of dental implants are verified in several studies (76-84), but there are still significant limitations especially related to digital impressions for FPD restorations on implants.

### **Fusion of data from CBCT and intraoral scanning**

Tooth supported static guided surgery use teeth as supporting structures for the surgical guides. Some systems apply technologies where the remaining dentition are digitized – either by scanning a plaster cast or by a direct intraoral surface scan. The digital representation of the remaining teeth is later fused with the tomographic data as a basis for the virtual plan of the implant surgery.

The actual fusion is based on a surface registration where the two datasets are superimposed based on anatomical features visible in both the surface scan and the virtual model from the tomographic dataset (85). This process may be hampered by artifacts in the virtual tomographic model caused by metallic dental restorations (86, 87), movement during the tomographic acquisition or suboptimal sensor rotation in the CBCT.

The presence of artifacts may impair the correct depiction of the dental anatomy and in turn affect the correct alignment (42, 87-89). The problem arises as well if the computer tomographs is acquired in intercuspatation position as the overlapping will result in inaccurate morphology (90). An accurate procedure for the alignment of CBCT and optical data are important to avoid the introduction of large deviations during the application of the virtual surgical plan. The verification of an optimal superimposition is user dependent and important for the result.

### **Different types of guided implant surgery**

The transfer of the virtual planned implant positions to the surgical positioning may be divided into two different systems: Jung and co-workers divided these in static and dynamic systems (91). The first method uses computed tomography data for digital planning and generates a static guide for implant placement. The second dynamic use a stereo vision triangulation setup to guide the implant into its predetermined position. The latter exclude time and cost associated with the production of the surgical guides and has the advantage that the surgeon may change the implant size, system, and end position during the surgery.

### **Dynamic guided implant surgery**

The dynamic systems communicate the determined implant positions using visual imaging tools on a computer monitor. The systems are dynamic as the surgeon are aided in real time by computer navigation technologies using real time using tracking sensors that monitor drill position (92-94). The surgeon has the possibility to change the position of the implant during the surgery based on the three-dimensional data and local conditions encountered during the

intervention. Manufacturers claim that the surgeons tactile feeling when drilling holes in the jawbone are improved. The exclusion of the surgical guide will as well improve the possibility to cool down the drills with saline during the drilling procedures. There are several dynamic systems available on the market. They are expensive and require a significant adaptation of the surgical procedures. The dynamic systems will on the other hand save total time as it is not necessary to produce a surgical template.

The static systems transfer the planned implant positions by a rigid template or guide containing holes to lead the drills and implants to their preplanned positions. Jung and co-workers stated that the static systems tended to be more accurate compared to the dynamic. The statement may be debated as most studies published on static systems are based on in vitro / ex vivo data whilst most dynamic studies are based on clinical in vivo data (95).

### **Template guided implant surgery – static**

A surgical template is manufactured based on the digital planning in static guided implant surgery. The template contains holes that corresponds with the planned implant positions. The surgeon use special drills that fits into the template holes in order to make holes (osteotomies) in the bone in the planned locations.

Some systems allow the surgeon to perform the osteotomies and install the implants through the guide – the so called fully guided implant surgery (96). The partially guided implant surgery will only allow the primary drilling holes to be performed through the surgical guide, but the implants need to be placed conventionally by free-hand installation without the use of the guide. Kühl and co-workers studied the differences between these two modalities and found no significant differences (97). Similar observation was done in a clinical study by

Geng and co-workers where they did not find any significant differences in accuracy between the partially and fully guided procedures (26). The 5th ITI consensus conference concluded, however, that the fully guided protocols yield a better accuracy than partially guided procedures (28). This statement was later confirmed in an RCT study by Younes and co-workers who concluded that fully guided surgery yields a better surgical accuracy compared to partially guided and free-hand surgery (8).

Static template guided surgery may be divided in three different categories according to the primary supporting structures on which the surgical templates are positioned: Bone, mucosa, or teeth (figure 1). A stable support for the template is important for the accuracy of the procedure (98) as the support ensure the identical position is transferred from the planning software to the patient.

A fourth group may be added as there are types of template guided surgery where mini-implants are added as support (99).

### **Bone supported guides**

Bone supported surgical guides rest on the alveolar bone. The adaptation between bone and template are based on three-dimensional data from computer tomographs. The accuracy of the volumetric 3D representation of bone from the CBTC may be suboptimal to secure an adequate support for the template. Studies have shown that metric measurements from CBCT's tend to underestimate the anatomic truth (100). Some authors have pointed out that bone supported guides require the elevation of an extensive mucoperiosteal flap to place the guide onto the bone, which may cause an increase in post-operative hemorrhage and pain (13).

### **Mucosal supported guides**

The mucosal supported guides rest on the soft tissues in the oral cavity. An exact replication of the soft tissues is important for the accuracy of the procedure. Volumetric CBCT data are used to secure the adaptation between the template and mucosa in the “double-scan technique”. A relined barium containing scan prosthesis, or a conventional full prosthesis, are worn by the patient during CBCT image acquisition. The prosthesis is later scanned in the CBCT and the two radiological volumes are aligned in the planning software. The prosthesis will have radiopaque fiducial markers to ensure an optimal alignment between the CBCT volumes. The inner surface of the prosthesis, extracted from the CBCT data, are used to secure an exact adaptation between the surgical template and oral mucosa. The guide is in most cases secured during surgery by anchor pins placed in bone as the mucosa offers limited retention for the guide (101). The anchor pins are placed in the alveolar bone from the vestibular side after the guide position is secured with a bite index.

### **Tooth supported guides**

Tooth supported guides rest on the residual dentition. The anatomical reproduction of teeth in computer tomographs may be suboptimal. The photons emitted by the computer tomograph will deflect as they hit metallic objects, and this occurs frequently as metals are common in dental restorative materials. The deflection may substantially degrade the reconstructed image quality (90) resulting in a suboptimal reproduction of teeth. Patient movement and suboptimal sensor movement may affect the quality as earlier mentioned. Consequently, CBCT image data are not ideal to use to secure an adequate adaptation between surgical templates and teeth. Some guided implant software uses a scanning template manufactured on a

conventional plaster cast. The patients wear the scanning template during CBCT acquisition. The scanning template is converted into a surgical guide after the planning procedures (102) ensuring the optimal adaptation between the template and teeth. Fiducial markers on the scanning template assure the transfer from the patient to the planning software.

Other systems use intraoral scanning data (103) as the basis for the adaptation between teeth and surgical guide. The surface scanning data are incorporated in the planning for tooth supported surgical templates as the 3D surface information will secure the needed close adaptation between the teeth and guide. An exact alignment between the CBCT and IO scan data is necessary to achieve sufficient accuracy of implant installation as the guide location is planned based on IO scanning data and the implant location are planned based on the CBCT data. The correct alignment between the volumetric 3D model from the computer tomograph and the surface scanning data from the intraoral scanner is secured by a best fit algorithm where anatomical data in both modalities are used to align the volumes. An incorrect alignment may introduce significant deviations between the planned and achieved implant positions.

There are, however, at present no consensus regarding the required metric size of the IO scans and CBCT volumes and how a reduced size will affect the accuracy.

Deviations in the superimposition procedure have been investigated and was explored in a study by Flugge and co-workers (88). They found that the segmentation of the tomographic volume, the user experience and the number of metallic dental restorations had significant influence on the registration accuracy. The mean deviation was 0.54 mm (0 - 24.8mm).

Abboud and coworkers have noted problems regarding fiducial marker registration in CBCT as noted earlier (51).

There is no scientifically based consensus on whether tooth or mucosa template support offer the best accuracy. Some authors claim more accuracy with tooth supported templates (7, 27, 104, 105) whereas other report better results with mucosal support (13, 106).

Temporary implants may be used as additional support for the templates and may yield to a more accurate surgical procedure (99, 107, 108).

### **Planning procedures – guided implant surgery**

Dedicated software is used to identify the ideal implant position in relation to the planned prosthetic restorations. This software allows the clinician to plan the implant position while taking vital anatomic structures into consideration. The patient anatomic reality can be evaluated based on 4 basic views: Axial, cross sectional, panoramic and a 3D reconstructed model. The implant may be projected onto the views and the relation between the anatomy and implant properly evaluated. Surface scanning files may be superimposed onto the views to observe the relation soft tissues, teeth, and underlying anatomy. Planned prosthetic restorations may as well be projected onto the views.

The preferred implant position is determined by the restorative team based on their knowledge on the implant system components, the anatomical limitations as well as prosthetic requirements. The implant needs to be fully embedded in bone while respecting distance to adjacent teeth as well as the buccal/palatal constraints and vital anatomical structures. The angulation of the implant axis determines the facial emergence profile of the implant restoration. A proper angulation will allow a screw-retained restoration as the screw access hole may be positioned in the cingulum or occlusal surface of the implant restoration. A cemented, non-retrievable, restoration will be the result if the optimal angulation is impossible



to achieve. An ideal relation between the implant and prosthetic restoration will give the possibility to obtain an optimal abutment design resulting in stable peri-implant tissues (109). An optimal abutment design will as well result in simplified hygiene measures (110). The actual implant components will be possible to visualize in the software and the need for components like angulated abutments will be possible to determine ahead of the treatment.

### **Surgical guide production**

Tahmaseb and co-workers differentiated static guided surgery systems by the production methods for the surgical templates (28). The group divided between laboratory based manual and rapid prototyping (RPT) production methods.

### **Manual production**

The manual production process is initiated by a conventional impression of the residual dentition. The impression is poured, and a 2-3 mm thermoplastic plate is pressed over the plaster cast. The prosthetic reconstructions are manufactured in wax. A putty impression is used to transfer the planned wax reconstruction to an acrylic material on top of the thermoplastic plate. The acrylic material will contain a radiopaque material to be visible on the computer tomograph. The scan prosthesis is carried by the patient during the tomographic acquisition. The desired reconstructions are thus visible in the planning software and ideal implant positions may be decided. Some systems use fiducial markers to precisely place the radiological stent into the tomographic data volume (111-114).

The planning procedure yields coordinates for each implant and holes corresponding to the planned implant positions are drilled into the template. Fortin and co-workers have published

several studies on this methodology (6, 112, 115-117). Already in 1995 Fortin and co-workers published the first scientific paper verifying the clinical application of laboratory manufactured surgical guides (102). The drilling of the planned holes is a manual process with the aid of a coordinate transfer apparatus or with a computer numerical controlled (CNC) unit (114, 118, 119). The deviation of the latter production was determined by Dreiseidler and co-workers to be less than 0,5 mm.

The deviation between the planned and achieved implant positions is the sum of all production steps:

1. Computer tomography acquisition
2. Scan prosthesis production
3. The drilling procedure to convert the scan prosthesis to a surgical template

An important advantage of the manual production method is the verification of the intraoral position of the guide which secures an identical position of the surgical guide in the planning software and during the surgical execution. Discrepancies in the positioning of the templates may cause inaccuracies (120).

Matta and co-workers have compared stereolithographic and thermoformed guides and found both methods to be clinically acceptable. Matta found a mean angle discrepancy of 3.5 degrees between the methods (121) based on data from 13 patients. The use of a radiographic template will have disadvantages as it is time consuming and has associated laboratory costs.

## **Digital additive manufacturing**

Surgical templates can be produced in a digital production process. Computer aided manufacturing is a fabrication of a physical object using 3D computer aided design (CAD). The creation of the object may be completed by additive manufacturing (3D printing) or subtractive manufacturing (milling) procedures. Kernen and co-workers studied the difference between analogue and digital fabrication of guides. They found that the differences between the planned and obtained implant positions was less with the digital production and concluded that there were more sources for inaccuracies in the laboratory-made surgical guides. (122). There is one major difference between the laboratory-based and the digital production: In the laboratory-based method there is a physical object which follows the guide production from acquisition of the radiographic template by the computer tomographs to the endpoint – the surgical guide. The conversion of the radiographic template into a surgical guide secures an identical position of the guide in the planning software and intraorally in the patient. The guide produced with the stereolithographic process is the physical result of a digital process. The digital production process consists of several steps - yet many of them have associated manual procedures and are prone to deviations.

The digital planning procedure is concluded by exporting the surgical guide from the software. The surgical guide will be exported as a 3 dimensional .stl file. The file is thereafter imported into a software for additive manufacturing which will prepare the 3D model for a digital production process. The software needs to calculate number of supports needed to place the surgical guide securely onto the building platform. The digital object is then sliced into layers which the printer will use in the printing process. The resulting file is exported to the stereolithographic printer. Two different 3D printing technologies are used to print surgical guides: The stereolithographic (SLA) and the digital light projector screen DLP printers. Both types use 3D printing technologies where a liquid photopolymer resin are

cured (solidified) by a light source. The SLA printers use galvanometers to navigate the light beam in a path which represents one layer of the part being built. The light source will cure the resin point by point making a solid layer of the part. The process is repeated until the part is complete. The DLP printer will project an image of the separate layer onto the resin which will increase the speed of the building process. The 2D image projected by the DLP printer is composed of pixels with a given resolution and is translated into voxels as the 3D part is being built. The building process will thus have a resulting resolution. The overall deviation in the digital production process of a stereolithographic surgical guide is evaluated in several studies to be less than 0.3 mm (123-125).

The stereolithographic production process introduces new and sensitive manual processes. After the part is built by the printer there are several post processing steps necessary (Figure 2) to complete the part. The first step is to clean excess uncured resin using isopropanol. The part is then post cured in UV light to enhance the mechanical properties. The completion of the surgical guide building process is to cut off the supports and install the metal sleeves. The processes may introduce deviations which may impact the result. Further scientific studies are needed to ascertain the significance of each process.

### **Clinical application of surgical templates**

The ideal implant position is determined preoperatively in guided implant surgery. It seems to be an increasing consensus that the use of guided implant surgery will have a potential to increase the quality of treatment outcomes (126). There are studies where the accuracy of conventional freehand surgery is compared to computer guided surgery. The studies conclude that guided implant surgery will result in a significant less variation between planned and obtained implant positions compared to the conventional free hand method (127). The few

randomized controlled trials comparing guided implant surgery with freehand conventional implant placement suggest greater accuracy, less morbidity measured as pain or swelling and less surgery time (5, 128, 129).

### **Learning curve**

The literature is not conclusive on whether the surgeons learning curve on template guided implant treatment is important (130). Some authors claim that variations in accuracy will decrease when the surgeon obtain experience in the application of guided implant surgery (130-133). A simplification of the procedures may probably increase the accuracy of the guided implant procedure even more as all necessary steps will contribute to the total deviation.

### **Implant survival**

The systematic reviews by Jung and coworkers and Schneider and coworkers evaluated both accuracy and clinical efficacy and concluded that different levels and quality of evidence were available (91, 134). Both authors found high implant survival rates after guided implant surgery, but the observation times were short. Jung and coworkers pointed out the need to identify clinical indications for guided surgery and a justification of the additional radiation doses, effort, and cost. Schneider and coworkers concluded that there is a need for clinical studies with longer observation periods and that the systems should be improved in terms of perioperative handling, accuracy, and prosthetic complications.

Deviation between the planned and achieved implant positions - inherent procedural errors  
There will always be a deviation between the planned and achieved implant positions, but it is important to reduce this discrepancy as much as possible. There is reason to believe that the

surgical application of the digital plan may cause a substantial part of the observed deviations as the actual surgical procedure will have associated inherent errors. Inherent errors are related to the equipment used for guided implant surgery. The templates will have holes made corresponding to the planned implant positions. The holes are reinforced with metallic sleeves to accommodate the drills and prevent wear of the acrylic material which may lead to inaccuracies. There must be a tolerance between the burs and the metal sleeves to allow the rotation of the burs inside the sleeves. The dimensional difference is necessary to avoid excessive friction between the implant carrier and sleeve. Lowering the tolerance may lead to friction between the bur and sleeve during implant installation and subsequent dislodgement of the guide. These inherent deviations were explored by Cassetta and co-workers in 2013 (135). When evaluating each mechanical component in the bur and sleeve system the authors found that the tolerance was the most important source of error. The investigation of one system indicated that the distance between the sleeve to the entry point in bone, the length of the sleeve as well as guide fixation and support area may affect observed deviations from the planned implant position. Sleeve length, especially in combination with long implants, is as well a source of potential inaccuracy and has been explored by other groups (136, 137). Brandt and coworkers recommended to use the shortest possible distance between the sleeve and alveolar ridge to optimize accuracy (138). Possible inaccuracies introduced by the sleeves and consequences by the wear of the sleeves during the drilling processes have been given attention (137). The wear will result in a larger tolerance between the sleeves and the burs, which may cause deviations in the implant installation procedure. In vitro research has concluded that wear of inserts, sleeves and burs may contribute to the total inaccuracy of the procedure (139, 140).

### **Mispositioning of the surgical guide**

D'Haese and co-workers studied the relation between implants within a patient that had received treatment with guided implant surgery (141). They observed that the mean deviation was significantly different compared to the inter-implant deviation. The results indicate that a major part of the deviations is caused by mispositioning of the surgical guide. It is therefore advisable to manufacture holes in the guide to allow the surgeon to verify complete seating before and during the drilling process.

### **Assessment of deviations between planned and achieved implant positions.**

There will always be some deviation between planned and achieved implant positions after guided implant surgery. The resulting deviation will be the sum of all deviations in the necessary steps in the planning and execution of the guided surgical procedure (142, 143).

The accuracy is calculated by matching the position of the planned implant in the guided surgery software with the actual position of the implant installed in the patient. Most studies determine the location of the achieved implant position by a postoperative computer tomograph. The procedure is described by Maes and co-workers (144).

The matching of the pre- and postoperative volume rendered models are sensitive to operator errors. There may as well be errors resulting from the tomographic acquisition. The metric differences are calculated based on the different points position in a 3-dimensional environment.

Four deviation parameters (Figure 3) can be measured:

- Deviation at the entry point / coronal center of the implant
- Deviation at the apical center of the implant
- Deviation in the long axis of the implant

-Deviation of the height / depth of the implant.

All parameters except the angular deviation, may be determined for both the coronal and the apical centers of the implant. Some studies use the term “global deviation” which is defined as the 3D distance between the coronal (or apical) center of the corresponding planned and placed implants. The 3D distance does not indicate the direction in which the difference is measured.

Other systems use a tooth-oriented system and report a metric buccal – lingual / mesial - distal deviation calculated from the coronal / apical centers of the corresponding planned and placed implants (145).

The use of different measurement methods makes a direct comparison between studies difficult.

*The depth deviation* is the distance between the coronal (or apical) center of the planned implant and the intersection point of the longitudinal axis of the planned implant with a plane parallel to the reference plane and through the coronal (or apical) center of the placed implant.

*The angular deviation* is calculated as the three-dimensional angle between the longitudinal axis of the planned and placed implant.

To establish the lateral deviation, a plane perpendicular to the longitudinal axis of the planned implant and through the coronal (or apical) center is defined and used as reference plane.

*The lateral deviation* is defined as the distance between the coronal (or apical) center of the planned implant and the intersection point of the longitudinal axis of the placed implant with the reference plane.

Another method to reduce the patient’s exposure to radiation is to manufacture a plaster cast containing implant replicas after the second stage surgery. A CBCT can then be used to



register the implant position in the cast. The postoperative CBCT may then be superimposed onto the preoperative CBCT and the metric deviations calculated.

This method for the calculation of deviations between the planned and achieved implant positions are verified by Nickenig and coworkers and Komiyama and coworkers (146, 147).

Other methods to calculate the deviations between the planned and achieved implant positions have been described. All methods are based on matching of pre- and postoperative models containing the implant positions. The models may be generated from computer tomographs or as alternative optical surface scanning (54, 148). The actual implant position may be calculated based on a visible scan body installed onto the implant which may be registered by a surface IO scanner (149, 150).

The implants 3-dimensional position in bone is calculated based on the superimposition of the dental anatomy from the IO scan (containing the scan body) onto the volumetric model generated from the computer tomograph.

The 3D model generated from the surface scanning are aligned with a volume rendered 3D model from the preoperative surgical planning. The matching process yields metric and angular values for the implant deviations. The patient advantage is obvious as the postoperative CBCT are eliminated. Brandt and co-workers have verified the actual procedure where the postoperative CBCT are replaced by a surface IO scan and concluded that this method is superior to the traditional postoperative CBCT based method (138).

### **Clinical outcome of guided implant surgery**

The accuracy of template guided implant surgery is the sum of all deviations in the necessary procedures from planning to execution. As it may contain the sum of errors in all procedures it may reach unacceptable levels.

D'Haese and co-workers reviewed a total of 31 clinical studies where 10 studies reported on accuracy (151). The group concluded that guided surgery yields a more accurate placement compared to freehand surgery. Furthermore, in respect of the possible deviations, the review suggested a 2mm safety zone apical to the planned positions to avoid injury to critical anatomical structures. Tahmaseb and co-workers analyzed the inaccuracy of guided implant surgery in the proceedings of the 5th International Team for Implantology Consensus Conference (28).

They concluded that an average deviation of 1.12 mm (maximum 4.5 mm) at the entry point of the implant was to be expected. The expected inaccuracy at the apex of the implant was 1.39 mm (maximum 7.1mm).

The values are in line with what van Assche and co-workers reported in their systematic review on 19 static guided implant surgery studies from 2012 (152).

The maximal deviations in the Tahmaseb study (in the proceedings of the 5th International Team for Implantology Consensus Conference) were reported in two papers and was related to external factors (153, 154).

Hultin and co-workers did a systematic review study on the clinical advantages of computer guided implant surgery (3). Apart from the presumed benefits of a more rapid procedure and a decreased patient discomfort, the authors pointed out that associated risks related to the deviations need to be considered. Twenty-eight original publications and 2 systematic reviews

with a total of 852 patients treated with 4032 implants using template guided surgery were included. The authors concluded that although limited evidence is available, guided implant treatment has at least as good implant survival as conventional protocols. Most of the studies included had an observational period of less than 2 years that limits the strength of the conclusion.

There will probably always be a certain amount of deviation between the planned and achieved implant positions when performing template guided surgery. A reasonable low and expected deviation may be acceptable whereas extreme outliers are unacceptable and may cause damage to vital structures. The expected deviations are built into many of the guided implant surgery software as “safety distances” and should be respected during the planning procedures. Tahmaseb and co-workers did a systematic review study including a meta-analysis of the accuracy including 24 clinical and preclinical studies. They found a mean deviation of 1.15mm (max 4.5mm) at the implants entry point and 1.39 mm (max 7.1mm) at the implants apex (28). Most guided implant software use a safety distance of 1.5mm. There are deviations between the planned and achieved implant positions associated with guided implant surgery. Some discrepancies are associated with the equipment used while others are dependent on the associated manual working procedures. The present thesis has the ambition to explore if the exclusion of some manual working procedures may decrease the discrepancy between the planned and achieved implant positions and thus increase the accuracy of the procedure.

**Aim:**

The present thesis aims to explore if digital replacement of manual procedures in guided implant surgery increases the accuracy of implant placement.

**Hypothesis:**

The null hypothesis ( $H_0$ ) is that the introduction of digital tools, to reduce the number of manual procedures in guided implant surgery, do not reduce the observed variations between planned and achieved implant positions.

**Aims:**Aim (Study No. 1)

The aim of this study was to evaluate the accuracy of the placement of dental implants when using digitally designed tooth-supported surgical guides. Furthermore, it was the aim to evaluate whether the recording of postoperative implant positions with the use of IO scanning was comparable with the one achieved with the use of CBCT, giving basis for a possible use of IO scanning in further clinical scientific studies.

Aim (Study No. 2)

This study was designed to evaluate the in vivo accuracy of digital planning and placement of implants using static tooth supported surgical guides.

Aim (Study No.3)

The study aspired to evaluate new digital planning procedures in a clinical study on guided implant treatment.

## **Materials and methods**

### **Experimental considerations**

#### **Research team**

The research team were comprised of three prosthodontists, two oral surgeons, one periodontist and one maxillofacial radiologist.

#### **Patient selection**

The patients included in the three studies were recruited among those referred to the Institute of Clinical Dentistry, University of Oslo in need for implant retained restorations. There were no limitations regarding age or gender to obtain a representative selection of patients. The study participants were included as one group in each study and received similar treatment based on static tooth supported guided implant surgery. 'A power calculation was not performed as the number of included subjects were limited by the available patients in the recruitment period.

#### **Inclusion / exclusion criteria**

The inclusion and exclusion criteria were based on the standard criteria for dental implant treatment at the University of Oslo.

The subjects had to be in good health and with a medical history that did not restrict the patient from undergoing dento-alveolar day surgery. The inclusion of patients was limited to ASA class I and II (155) .

The subjects included had to be over 18 years old, partially dentate, be candidates for partial reconstructions using dental implants and willing to undergo a two-stage surgical procedure.

Subjects presenting the following conditions were excluded from the studies:

- (a) clinical and radiographic signs of untreated or active periodontal disease
- (b) previous intake of bisphosphonates
- (c) current use of systemic corticosteroids
- (d) documented therapeutic radiation to the head and neck
- (e) uncontrolled diabetes
- (f) smoking habit
- (g) pregnancy or lactating

Patients accepted for the studies had to sign an informed consent form prior to inclusion and the patients had the right to withdraw from the study at any time during the study period.

## **Procedures**

### **Planning procedures**

Planning procedures for guided implant surgery is an essential part of the treatment. The three studies in this thesis differ significantly in the degree of manual and digital procedures necessary in the planning and manufacturing of the guides. The differences are important as the surgical procedures are similar in all studies. The manually manufactured scan prosthesis based on a conventional plater cast in study No 1 is replaced by a manually manufactured, and digitized, plaster cast in study No 2. The manual working procedures are replaced by an IO

scan in study No 3. The replacement of a plaster cast is a crucial step as this ascertain the adaptation between the supporting teeth and surgical guides, as well as the identical position of the guide in the planning software and the patients mouth.

The manual working procedures associated with the prosthetic planning procedures in study No 1 imply additional expenditure and time. Some of the manual working procedures were excluded in study No 2, but both studies used dental technicians in the planning procedure. In study no. 3 all planning work with the design and manufacturing of the guides were done by the dentist without input from the dental technician.

The prosthetic treatment planning was performed by a prosthodontist and a manual wax up was made by a dental technician based on the prosthetic plan in study No 1. In this study a scanning template based on the wax-up was fabricated from acrylic resin containing 30% barium sulphate based on a thermoplastic acrylic plate. A template (TempliX, Institut Straumann AG, Basel, Switzerland) containing three fiducial markers made from titanium was fused onto the scanning template. The intraoral fit of the scanning template was verified before the computed tomographies were acquired.

Full-arch silicone impressions (Impregum/Permadyne, 3M ESPE, St. Paul, MN, USA) were performed of all included patients in study No 2. The impressions were poured with GC FujiRock (GC Europe, Leuven, Belgium). Plaster casts were digitized in a dental scanner (3Shape D700, 3Shape, Copenhagen, Denmark) and subsequently imported into the digital treatment planning system (3Shape Dental System, 3Shape, Copenhagen, Denmark).

The desired dental restorations were subsequently designed in the 3D digital environment by a dental technician. The resulting files, i.e., a digital file of the plaster cast and the desired reconstructions were fused into a standard tessellation language (.stl) file by dedicated software (3Shape, Copenhagen, Denmark). Full arch digital impressions were made on a TRIOS 2 IO scanner (3Shape, Copenhagen, Denmark) in study No 3. The resulting IO

scans were transferred through 3Shape Communicate, a web-based file transmission system, and imported into 3Shape Implant Studio (3Shape, Copenhagen, Denmark). The IO scan was superimposed and aligned onto the CBCT using a best-fit surface alignment procedure and verified by anatomical landmarks by the prosthodontist (HS). The superimposition of a file containing the dental anatomy onto the computer tomograph is a sensitive part of the guided implant planning procedure. Incorrect alignment may have implications for the accuracy of the procedure (88). A superimposition procedure was not necessary in study No 1 as the system used a scan prosthesis. Trained system engineers performing the superimposition in study No 2 may have had a positive effect on the measured accuracy, whereas the prosthodontist performing the alignment may be a weakness in study No 3.

### **Cone beam computer tomographies**

Two different computer tomographs were used in the three studies.

Cone beam computer tomographies (CBCT) were acquired with a Scanora 3D (Soredex, Tuusula, Finland) in studies No 1 and 2. The Scanora CBCT were replaced by a Morita Accuitomo 170 (J Morita Mfg. Corp., Kyoto, Japan) during the study period and this CBCT was used in study No 3. The same oral and maxillofacial radiologist specialist performed the CBCT recordings in all three studies. A large field of view (FOV) were selected in all included studies to secure an optimal alignment between the CBCT volumes and surface scans. The large FOV was as well necessary in study No 1 to cover the fiducial markers attached to the scanning templates.

The estimated DAP dose was 404 Gy $\text{mm}^2$  in the first two studies and 1000 Gy $\text{mm}^2$  in study No3. The tomographs were exported in DICOM format in all included studies. Slice thickness and spacing were 0.35 mm in studies 1 and 2 and was lowered to 0.25 mm in study No 3 according to recommendations from the radiologist.



The application of two different computer tomographs is a weakness in the thesis as the metric accuracy may differ between different tomographs (51).

The implant positions were determined in relation to the planned prosthetic reconstructions.

Three different guided surgery software were used in the studies: coDiagnostiX (Institut Straumann AG, Basel Switzerland) in study No1, Simplant (Materialise, Leuven, Belgium) in study No 2 and 3Shape Implant Studio (3Shape, Copenhagen Denmark) in study No 3.

The ideal implant position was planned in the software based on the following criteria in all studies: The implant body fully embedded in alveolar bone while respecting the proper distance to adjacent teeth as well as the buccal and palatal/lingual aspect according to the standards at the Section of Oral Surgery and Oral medicine, Faculty of Dentistry, University of Oslo. A minimum of 1.5mm distance to the buccal cortical bone as well as 1.5 mm to neighboring teeth. Implant body length not exceeding a 2mm safety distance to vital anatomical structures. The inclination of the implant body enabled a screw retained restoration with the screw access hole preferably placed on the occlusal/palatal surfaces of the restorations.

The calculated positions of the planned implants were exported from the software as coordinates and sent to the dental technician in study No 1. A manual process converted the radiographic scanning template into a surgical guide: The dental technician mounted the scanning template into a special laboratory appliance: (GonyX, IVS-Solutions, Chemnitz, Germany). The coordinates generated by the software were entered into the laboratory appliance manually. Holes were then drilled into the guide leaded by the coordinates. Metal sleeves (T-Sleeves Institut Straumann AG, Basel, Switzerland) were glued in the prepared holes. The guide sleeves were 5 mm in length and 5 mm in diameter.

The planning and production of surgical guides were fully digital in studies 2 and 3. A digital file containing the planned implant positions was sent through the internet to Materialise in

study No 2. The Surgiguide® surgical guides were designed by Materialise (Materialise, Leuven, Belgium) and the final guide design was approved by the restorative team before manufacturing. The guides were produced by Materialise in a stereolithographic process where the details regarding materials and machines were undisclosed to the research team. The implant positions and surgical guides were totally designed by the restorative team and exported as an .stl file in study No 3. The following settings were used: guide thickness 2 mm, 0.075 mm offset between teeth and guide, 0.00 retention amount and 0.030 mm offset between sleeve and template.

The .stl file was transferred via the internet to Innovation Meditech (Innovation Meditech, Unna Germany). The guides were then produced in a stereolithographic process by illuminating light-polymerizing resin with a laser. The material used was Dreve ProDiMed M120 (Dreve Dentamid GmbH, Unna, Germany).

### **Surgical procedures**

All surgical procedures were performed by two oral and maxillofacial surgeons. Patients received 600 mg of clindamycin 45 minutes preoperatively. Local infiltration anesthesia with a vasoconstrictor (Xylocaine Dental with adrenaline TM, Dentsply, York, USA) was used during the surgical procedures. Patients rinsed with chlorhexidine gluconate 0.2 mg/mL for 60 seconds (Corsodyl TM, Glaxo Smith Kline, Oslo, Norway) prior to initiation of surgery. After verifying anesthesia, a supra-crestal incision without vertical releasing incisions was performed before reflecting a mucoperiosteal flap. All implants were installed in healed sites. The osteotomies were prepared according to the manufacturer's instructions (Institut Straumann AG, Basel, Switzerland) and (Dentsply Implants AB, Mølnadal Sweden) using the surgical guides with continuous sterile saline irrigation. The surgical procedures were performed using the manufacturers, (Institut Straumann AG, Basel, Switzerland) and

(Dentsply Implants AB, Mølndal Sweden) surgical equipment made for guided implant surgery: Straumann Guided Surgery concept is based on a sleeve in sleeve system where drill handles accommodate the different burs in one guide/sleeve. The burs have depth indicators engraved giving the depth of the osteotomies. An implant (Bone Level, RC, guided, SLActive®, Institut Straumann AG, Basel, Switzerland) was then placed using the surgical guide. The implant carrier is especially made for guided implant surgery and fits in the Straumann drill handle. A closure screw was placed for the submerged healing of the implant. Astra Tech Implant guided surgery concept is based on a sleeve on drill system where the different guided surgical drills have sleeves mounted onto the drill. The bur/sleeves fit in the sleeve mounted in the surgical template. The burs have depth stops giving the depth of the osteotomies. The implants were inserted, and primary stability verified using an adjustable torque wrench (Salvin-Torq, Salvin Dental Specialties Inc. Charlotte, N.C., USA) set at 15 Ncm.

Repositioning of the mucoperiosteal flap was performed using non-resorbable pseudo-monofilament suture (Supramid®, B. Braun Melsungen AG, Melsungen, Germany).

Ibuprofen (400 mg) and acetaminophen (500 mg) was prescribed for every 6 hours for the first 48 hours after surgery and thereafter as needed. The patients were instructed to use chlorhexidine gluconate 0.2 mg/mL mouth rinse twice daily for one week. Sutures were removed one-week postoperatively. Oral hygiene was verified and reinstructed if needed.

A two-stage surgery procedure was followed, and all implants were thus submerged during the healing period of 12 to 15 weeks according to the standard regimen at the Faculty of Dentistry, University of Oslo. The implants were exposed into the oral cavity after a separate surgical procedure with mounting of a healing abutment.

Straumann BL implants were used in study No 1 and 3. Dentsply Astra implants EV were used in study No 2 and 3. Straumann BL implants were used in study on and three. There are

some procedural differences between the two implant systems applied, however, the surgeons were experienced in both systems, so the effect of the differences are low.

### **Data collection**

The included studies in this thesis were compared by the differences between the planned and achieved implant positions after guided implant surgery. The measured deviations are the sum of deviations related to all necessary steps from planning to execution. The methodology used to determine the postoperative position of the implants differed between the studies regarding the metrology software used to calculate the differences between the planned and achieved implant positions. The metrology software measures the deviations differently and apply undisclosed algorithms for the calculations. This may be a limitation because it is not possible to verify the calculations.

The metric deviations between the planned and achieved implant positions in study No 1 are described with terms commonly given for orientation within the oral cavity.

Vestibular – oral, mesial-distal, and apical were used to describe the direction of the metric differences. Coordinates of the implants apical and coronal points were defined and used for the calculations (Figure 4, figure 5). Differences in angulation were calculated based on the 3D angle between the longitudinal axis of the planned and placed implants. A 3D offset value was calculated. The 3D offset was defined as the 3D distance between the coronal centers of the corresponding planned and placed implants. All implants in study No 1 were scanned with an iTero IO scanner after the appropriate scan bodies (Straumann Mono, Institut Straumann AG, Basel, Switzerland) were installed onto the implants.

A “Standard Tessellation Language” (. stl) file was exported based on the scan file. The file contained the surface geometry of the dentition as well as the scan bodies. The file was

subsequently imported into the coDiagnostiX treatment evaluation module. The volume-rendered 3D model generated from the preoperative CBCT segmented with a threshold of 1200 Hounsfield units (H) was aligned with the postoperative surface scan. No manual alignment was performed. The software detected the scan bodies in the postoperative IO scan automatically and generated metric values for the deviations between the planned and achieved implant positions.

The postoperative CBCTs in study No 1 were taken 12-15 weeks after surgery. The settings were identical to the preoperative tomographs.

The resulting volume dataset was imported into the coDiagnostix treatment evaluation module as DICOM files and segmented with a threshold of 500H. The postoperative CBCTs containing visible representations of the implants were aligned with the preoperative CBCTs containing the planned implants using anatomical landmarks. The software calculated the metric deviations based on the alignment by a proprietary algorithm.

The achieved implant positions were assessed using the procedure described by Nickenig and Eitner in study No 2 (146). An implant level impression was made after completion of the surgical treatment. Impressions were taken with the corresponding implant impression copings and Impregum impression material (Impregum 3M ESPE, St. Paul, MN, USA). The impression was poured with GC FujiRock (GC Europe, Leuven, Belgium) after implant replicas had been attached to the impression copings. The implant replicas were identical to the implants placed. A postoperative CBCT was taken of the master cast model. The postoperative scan was superimposed onto the preoperative scan containing the virtually placed implants using specialized metrology software (Mimics, Materialise, Leuven, Belgium). Coordinates of the implants apical and coronal points were defined and used for the calculations (figure 6, figure 7).

The difference between the planned and achieved implant positions was calculated in the software after two different operators had verified the superimposition.

The Mimics software manual procedure was followed:

*An object registration was performed to evaluate deviations between the planned and achieved implant positions. The preoperative 3D representations of the jaws were aligned with their counterparts in the postoperative images. An iterative closest point algorithm was used to match the jaws. The established coordinate transformation operation was also applied to the 3D representations of the planned implants allowing for a comparison with achieved postoperative implant position. All calculations were performed in the Mimics® software (Materialise, Leuven, Belgium). Four parameters were defined and calculated: global, angular, depth, and lateral deviation. All parameters except the angular deviation were determined for both the coronal and apical centers. Global deviation was defined as the metric distance between the coronal/apical centers of the implants, while angular deviation was calculated as the angle between the longitudinal axes of the planned and placed implants. To establish lateral deviation, a plane through the coronal (or apical) center of the planned implant perpendicular to its longitudinal axis was defined and referred to as the reference plane. Lateral deviation was calculated as the distance between the coronal (or apical) center of the planned implant and the intersection point of the longitudinal axis of the placed implant with the reference plane.*

*Depth deviation was calculated as the distance between the coronal (or apical) center of the planned implant and the intersection point of the longitudinal axis of the planned implant with a plane running through the coronal (or apical) center of the placed implant parallel to the reference plane.*

The software calculated the metric deviations based on the alignment by a proprietary algorithm in the Mimics software. The algorithm is an industrial secret and not available for the research group.

Calculation of the difference between the planned and achieved implant positions was performed in 3Shape Convince (3Shape, Copenhagen, Denmark) in study No 3. The planning procedure in 3Shape Implant Studio yielded a digital model from the preoperative IO scan that included a representation of the planned implant. All implants in study No 3 were scanned with a 3Shape Trios 2 IO scanner after the appropriate scan bodies (Straumann Mono, Institut Straumann AG, Basel, Switzerland and ELOS Accurate scan bodies for Dentsply Implants EV) were installed on the implants. The postoperative IO scan yielded a 3D model in which the scan body was clearly visible. Both digital models were imported into 3Shape Convince. The models were matched with an iterative closest point algorithm and verified using anatomical landmarks. The following procedure was used to establish the metric deviations: Planes through the coronal (IC1) and apical (IC2) centers of the planned implant perpendicular to its longitudinal axis were defined and referred to as the reference planes. The IC1 and IC2 points as well as the axis direction (IC vector) were defined with coordinates in the X, Y and Z dimensions (figure 8).

Achieved implant position were calculated with the following protocol:

A plane through the coronal center (SB0) of the scan body perpendicular to its longitudinal axis was defined and referred to as the reference plane. The longitudinal axis (SB vector) through the coronal center was defined. The SB1 and SB2 points of the achieved implant position were defined with coordinates in the X, Y and Z dimensions. Scan body length from the coronal center of the implant to the top of the scan body was known.

The difference between the planned and achieved implant position was calculated in Microsoft Excel (Microsoft Inc, Redmond, Washington, USA) based on the calculated implant positions in 3Shape Convince. The following parameters were calculated: Global difference between the coronal and apical centers of the planned and achieved implant positions, angular difference between the longitudinal axes of the planned and achieved implant positions, and the depth difference measured at the coronal center of the planned and achieved implant positions. The calculations were performed based on proprietary algorithms. The algorithms are an industrial secret and not available for the research group. A negative value for the depth measurement indicated that the achieved implant position was deeper compared to the planned position.

## **Statistics**

### Primary outcome variables

The metric deviations were calculated in three different metrology software's. The studies were compared by the four common metric parameters in the three studies: Depth, angle, and global deviations at the coronal and apical points.

Descriptive statistics were used to evaluate the differences between the planned and achieved implant positions as well as the difference between the postoperative CBCT and IO scan modalities in study No 1. The analysis of the data was performed by descriptive statistical analysis; mean +/- standard deviation (SD) and ranges. A 95% confidence interval was calculated for each parameter. The normality of the difference between the two samples was tested graphically on a histogram and using the Shapiro-Wilk test. Paired sample t-test was used to determine whether the mean difference between the two sets of observations was zero, when the normality assumption was satisfied; otherwise, the Wilcoxon test was used.



Statistical analyses were performed by using the Statistical Package - SPSS 17.0 (SPSS Statistics, Chicago, Illinois, USA); the level of significance was set to  $p < 0.05$ .

Descriptive statistics were used to evaluate the differences between the planned and achieved implant positions in study No 2. The analysis of the data was performed by descriptive statistical analysis; mean +/- standard deviation (SD) and ranges were calculated in Microsoft Excel (Microsoft Inc, Redmond, Washington, USA).

Descriptive statistics were used to evaluate the differences between the planned and achieved implant positions in study No 3. The analysis of the data was performed by descriptive statistical analysis; mean +/- standard deviation (SD) and ranges was calculated in Microsoft Excel (Microsoft Inc, Redmond, Washington, USA).

Statistical comparison of common parameters in the three included studies.

Normality of continuous variables was tested by Shapiro-Wilk test and histogram.

Due to the low sample size and non-normal distribution of the continuous variables (depth, angle and global) Kruskal-Wallis ANOVA was used to detect median differences of continuous, numerical variables between the three groups (study 1, 2 and 3), while Dunn's test was used for pairwise multiple comparison.

STATA (Stata version 14.0; College Station, TX USA) were used for the statistical analysis.

### **Limitations**

The present thesis includes a low sample size, and the comparisons were performed on implant level. This will obviously limit the statistical power and the results should be interpreted with caution.

## Results

The three studies included in this thesis were prospective nonrandomized clinical studies.

### Study No. 1

Thirteen subjects were included in this study. Twenty-eight implants with a sandblasted and acid-etched surface were placed in thirteen patients using thirteen tooth-supported surgical guides.

Three implants were lost during the study period.

The difference between the planned and achieved implant positions were measured based on postoperative CBCT and IO scanning. Mean differences between the planned and achieved implant positions measured on CBCT were:

Angle 2.58 degrees (SD 2.07; range 10.60 – 0.70).

Coronal point:

3D offset 0.90 (SD 0.44; range 1.91 – 0.03), distal displacement 0.29 (SD 0.25; range 0 – 1.03). Vestibular displacement 0.55 (SD 0.42; range 1.66 – 0.3), apical displacement 0.5 (SD 0.38; SD 1.79 - 0).

Apical point:

3D offset 1.11 (SD 0.44; SD 2.1 – 0.44), distal displacement 0.45 (SD 0.39; range (1.45 – 0.4), vestibular displacement 0.74 (SD 0.39; range 1.44 – 0.12), apical displacement 0.49 (SD 0.38; range 1.78 – 0.1).

The study did not resolve any significant differences in the identified position of the implants postoperatively as measured by CBCT or IO scanning, except for the apical deviations at the coronal and apical points.

The angular difference between CBCT and IO scanning at the coronal point was  $-0.011 (\pm 0.6)$  degrees whereas the 3D deviation difference was  $0.03(\pm 0.17)$  mm. The distal deviation difference between CBCT and IO scanning was  $0.01(\pm 0.16)$  mm, the vestibular deviation difference  $0.033(\pm 0.16)$  mm and the apical deviation difference was  $0.09(\pm 0.16)$  mm. The 3D deviation difference at the apical point was  $0.04(\pm 0.22)$  mm. The distal deviation difference between CBCT and IO scanning was  $0.06(\pm 0.19)$  mm, the vestibular deviation difference  $0.032(\pm 0.23)$  mm and the apical deviation difference was  $0.09(\pm 0.16)$  mm.

### **Study No. 2**

Ten patients and 31 implants were included in this clinical trial. All implants were placed in a fully guided procedure using 12 tooth supported guides. No implants were lost during the follow-up period.

Coronal point:

Mean global deviation was 1.14 mm (SD 0.38; range 0.56–2.11). Depth deviation between the planned and achieved implant positions measured at the coronal point was 0.93 mm (SD 0.43; range 0.25–1.88).

Lateral deviation was 0.57 mm (SD 0.28; range 0.04–1.09) and angular deviation was 3.33 degrees (SD 3.46; range 0.00–19.04).

Apical point:

Mean global deviation was 1.48 mm (SD 0.47; range 0.62 – 2.76). Depth deviation between the planned and achieved implant positions measured at the apical point was 0.96 mm (SD 0.42; range 0.25 – 1.84). Lateral deviation was 1.06 (SD 0.5; range 0.14 – 2.75)

### **Study No. 3**

Twenty-seven implants were placed in 20 patients using twenty tooth supported surgical templates after a digital planning procedure. No implants were lost during the study period. Average angle deviation was 3.85 degrees (SD 1.83; Range 8.6–1.25).

Coronal point:

The average lateral deviation measured at the coronal point was 1.05 mm (SD 0.59; Range 2.74–0.36). Average lateral deviation measured at the apical point was 1.63 mm (SD 1.05; Range 5.16–0.56). Average depth displacement was + 0.48 mm (SD 0.50; Range 1.33– 0.52).

### **Comparison included studies**

All patients were placed in one study group and the primary outcome measures were calculations of deviations between the planned and achieved implant positions (table 1).

All implants were installed using fully guided, tooth supported, static implant surgery using two implant systems. Forty-three patients received treatment with 86 dental implants in the included clinical studies in this thesis. 10 males and 33 females with a mean age of 52 years. 55 implants were installed in the upper jaw whereas 31 implants were installed in the lower jaw. Three implants were lost. The metric deviations were calculated in three different metrology software.

The studies were compared by the four common metric parameters: Depth, angle as well as global deviations at the coronal and apical points.

Metric deviations were extracted from the metrology software's and analyzed in STATA v14. Depth, angle, and global deviations at the apical point showed significant median differences between the studies. All differences were considered significant at  $p < 0.05$ .

## **Discussion**

### **Introduction**

The quality of the planning ahead of a complicated medical procedure such as dental implant surgery is important for the result. A prosthodontist and a surgeon will in most cases collaborate in the planning procedure. Prosthetically driven implant surgery is today established as the fundamental concept giving the prosthodontist a leading role in the planning process. The planned implant position is subtracted from the ideal prosthetic reconstruction in each case: “The crown down implant planning”. There will in most cases be necessary to make compromises between the prosthetic and surgical demands. Guided implant software in which both the placement of the planned implant and the restoration are visible permits the compromises to be made based on the actual clinical situation (156, 157).

All elements in a prosthetic rehabilitation are, however, not possible to plan in a computer. A concise and formulated plan considering not only the local treatment need, but a conclusive plan for the patient’s total need for oral rehabilitation, will lead to an optimal treatment result. The site-specific implant planning may be initiated after the prosthodontist has formulated a conclusive plan based on the restorative treatment need.

The planned prosthetic restoration may be designed preoperatively and integrated into the surgical planning software as demonstrated in study No 1, 2 and 3.

The prosthodontist is educated to perform this evaluation and planning based on established prosthetic treatment principles as well as a thorough knowledge about the patient’s restorative

requirements. Implant planning software with the possibility to design the prosthetic reconstruction will probably lead to a better result. The prosthodontist will then have the possibility to plan a treatment in the context of the total rehabilitation plan for the individual patient. The implant planning software is thus not just a surgical, but also a prosthetic tool to plan prosthetic implant-based reconstructions.

### **Case preparation for the digital planning procedure**

Several preparatory procedures are necessary to be performed prior to the digital implant planning procedure (figure 9).

Conventional impressions were performed as the initial procedural step in study No 1 and 2. Inaccuracies associated with conventional impressions are well documented in the literature (158). Inaccuracies in the impressions and subsequent pouring may affect the correct replication of teeth. Plaster casts were the basis for an accurate adaptation of the surgical guides to the remaining teeth in studies 1 and 2. These processes may thus have had impact on the adaptation between surgical guides and supporting teeth. The plaster casts were scanned by a desktop scanner in study number 2. Conventional impressions and plaster casts were replaced by intraoral scans in study No 3.

The accuracy of an intraoral scan is described by the term's trueness and precision. The terms are described in the ISO standard: ISO 5725-1. Trueness describes how far the measurements are from the described object. Precision describes the difference between the different measurements. IO scan accuracy is proposed in the literature to be at least as accurate as the conventional impression procedure (159). There are limiting factors related to type of scanner, scan procedure as well as scan area (160).

IO scan files are composed of polygon meshes where meeting points (vertexes) between the polygons are described in a three-dimensional coordinate system. The resulting polygon mesh

will have a resolution related to the distance between the points. The area between the points will not be accurately described - but estimated by the computer through flat triangles connecting the known vertexes. Surfaces containing sharp edges or strong curvatures will have imperfections when they are digitized by an intraoral scanner. It follows that only flat surfaces will be correctly described from a geometric standpoint. Stl files describing objects containing curved structures will often be large as the number of vertexes increase. The accuracy (trueness) will in some cases suffer to keep the files manageable in a computer. The in vivo application of intraoral scanners will introduce factors that will affect the trueness of the resulting 3D model as a suboptimal scan procedure may affect the trueness of the polygon mesh.

There are as well differences between different scanners with regard to trueness (73, 161). Even though there are problems associated with digital impressions a growing number of clinicians see the advantages over conventional impressions (162). These are obtained through direct visualization of the model, a more time efficient procedure and easy repeatability.

As the IO scan stl file is used as a basis for the stereolithographic surgical guide the technological limitations of IO scans may have an implication for the total accuracy of the procedure in study No 3.

Manufacturers try to compensate for a suboptimal surface description by the introduction of a compensation factor in the guided implant software: An “offset” (compensatory distance) may be set in the guided implant software to be able to seat the guide fully on the supporting tissues. The offset creates a distance between the oral surfaces (in the stl file) and the inner surface of the guide. A common value in several software is 0.2mm. The general compensation will probably not secure the ideal adaptation between the guide and supporting tissues.

The inner part of the guides in study No 2 and 3 were based on digital reproductions of remaining teeth. Deficiencies in the digital description of the anatomical surfaces may result in a difference between the position of the surgical guide in the software and the patient's mouth.

The planned prosthetic restorations were designed by a dental technician in study No 1 and 2 based on conventional impressions. The planned restorations were sculpted in wax on articulated casts by a dental technician in study No 1. A silicone buccal index was made based on the wax. A thermoplastic disc was pressed onto the cast and the wax replica of the planned restorations was duplicated in barium containing acrylic based on the buccal index. The result of this procedure was a scan prosthesis which the patient wore during the tomographic acquisition.

The prosthetic plan was digitally designed by a dental technician in study No 2.

The design could be verified by the prosthodontist after the digital plan was imported into the implant planning software. There are as of today not possible to simulate articulation movements in the software.

The digital design process made the collaboration between the dental technician and prosthodontist more convenient. Revisions on the prosthetic design was faster as new or revised design files could be transferred electronically. The planned prosthetic restorations were designed in the implant planning software by the prosthodontist in study No 3.

Revisions to the prosthetic plan were more convenient to perform compared to the procedures in studies No 1 and 2 as the prosthodontist performed all prosthetic planning operations.

The substitution of the manual wax-up with a digital design procedure is probably of minor importance for the accuracy of the guided implant procedure as the wax up is not being used for guide manufacturing.



## **CBCT acquisition, segmentation, and superimposition**

The clinical application of guided implant surgery is based on acquisition of tomographic data of the patient. The increased dose of ionic radiation needs to be justified as it may implicate an increased risk of cancer (163). The publications seeking to justify the use of tomographic data in implant planning are based on the fundamental principle of radioprotection: ALARA (: Keep radiation dose As Low As Reasonably Achievable) (164). The European Academy of Dento-maxillofacial Radiology published 20 basic principles, for the use of tomographs in 2009 (165). European Academy for Osseointegration has as well published guidelines for the application in dental implant treatment (46). It is difficult to establish specific guidelines as there are large differences in ionic radiation between different CBCT machines (53). The mere focus on FOV (field of view) does not imply a reduction as there are many other parameters that has a significant influence on radiation dose. As new treatment concepts evolve and new machines are introduced, a new concept for ionic radiation protection has been proposed: The ALADA concept (As low as diagnostically acceptable) (166). The concept focus on the selection of exposure factors to decrease the radiation dose while maintaining a sufficient image quality.

Errors may arise from the acquisition of the tomographic volumes. Type of CBCT, conversion, segmentation, volume rendering, and manual removal of streak artefacts are technique sensitive procedures and may have an implication for the total accuracy of the procedure (53). Patient movement during CBCT acquisition may affect the isometric 3D representation of the volume and thus have a negative effect on the accuracy of the procedure (167). The metric accuracy of the tomographic volume will as well be dependent on system specific voxel size, segmentation algorithms as well as the mechanical accuracy of the

individual CBCT machine (51). Different CBCT machines will have technical differences influencing patient radiation dose as well as resolution and slice thickness (168). It is important to consider the amount of radiation necessary to acquire an image with sufficient detail considering the ALARA principle. Another important aspect is the field of view (FOV). A larger FOV will directly influence radiation dose and need to be kept as small as possible. A scan area covering the dental arch is necessary in guided implant surgery for correct superimposition of an IO scan and stability of the guide (169). Choosing a suitable voxel size for guided surgery will as well affect the radiation dose to the patient. A smaller voxel size will implicate more scan time for acquisition and a larger dose (170, 171). Modern CBCT machines use software reconstruction algorithms to reduce scan times by keeping reconstructed voxels (172). Dach and coworkers found that shorter scan times did not affect linear accuracy for smaller voxel sizes, and this may be important in order to reduce radiation doses. The amount of energy used to acquire a CBCT image is as well important to consider. The intensity of the x-ray beam (milliamperes - mAh) and the penetration level (kilovolts – KV) are directly influencing the absorbed dose to the patient. The KV will influence image contrast and noise. It is therefore advisable to reduce mAh to reduce the dose to the patient. A moderate reduction of mAh will not affect bone measurements for implant planning (173). Clinicians need to be aware of the CBCT related challenges and the potential implications it may have for the accuracy of the guided surgical procedure as well as the radiation dose to the patient. The present studies had an oral and maxillofacial radiologist performing the tomographs. Two different CBCTs were used in the studies. This may have had implications measured results presented in this thesis. The FOV, KV and mAh were chosen based on the ALADA concept and were similar in the different studies.

## **The guided implant software**

The tomographic volume was imported into the guided implant software after acquisition as multiple two-dimensional sliced Dicom files. The 2D files were converted into a volume rendered three-dimensional anatomic model in the segmentation process. The segmentation procedures are sensitive with a significant learning curve.

The tomographic volume may be divided into separate parts based on the attenuation of the different types of tissue. A series of tools were implemented to manipulate the data to optimize the 3D model. Parts of the 3D representation may be compromised because of scattering effects. Studies have documented that segmentations are more difficult on patients with a large number of metal/zirconia restorations (88, 89) due to scattering effects.

Cutting tools may in such instances be used to remove artifacts on the 3D model. Other techniques exist where 2D files containing scatter are removed from the stack.

A thorough training and experience on the procedure will increase the quality of the segmentations as the procedure is complex.

The accuracy of the guided implant procedure relies on an identical position of the surgical guide in the planning software and subsequently intraorally.

The conventional impression, plaster cast and radiological stent with fiducial markers in study No 1 secured the transfer of the virtual plan to the surgical instance as there were a physical object, the stent, throughout the planning and execution.

There are, however, associated deviations connected to the matching of the fiducial markers on the radiological stent to the corresponding markers in the planning software. An imprecise positioning of the radiographic stent during CBCT acquisition may have introduced inaccuracies in this modality.

The manual production of surgical guides was replaced by surface scanning in study No 2 and 3. The surface scans were the basis for adaptation between the surgical guide and remaining teeth whereas the implants were virtually placed in the 3D anatomical model. A correct alignment of the surface scan onto the tomographic volume is highly important (88). An incorrect alignment may induce substantial deviations between the planned and achieved implant positions. Superimposition/alignment of the tomographic volumes and surface scan polygon mesh are in many cases difficult. Most software have integrated functionality using an iterative closest point algorithm which will propose a superimposition of the polygon mesh. A user verification of correct alignment may be complicated by metallic artefacts in the tomographic volume or incorrect segmentation procedures. The presence of artefacts will make it difficult to identify characteristic anatomy used to verify the correct alignment. The actual procedure of alignment should be regarded as a manual procedure and may affect results to a high degree. The deviations arising from an inaccurate alignment were documented in a recent study by Flügge and coworkers (88). The authors concluded that registration accuracy was influenced by pre-processing of the imported data as well as by the operator. Their findings yielded mean deviations between surface scan and CBCT models of 0.54 mm(mean). There was a difference for default (0.69 mm) and manual (0.4 mm) segmentations. The maximum deviations were 24.8 mm and 9.1mm. The study documented the importance of the superimposition / registration procedure and the possibility for a clinically non-acceptable total deviation. The study documented the importance of user awareness of this problem as well and that the automatic segmentations need to be closely verified. Deviations between the planned and achieved implant positions caused by suboptimal superimposition will mainly cause a 3D global deviation. The virtual surgical guide will have a different position compared to the intraoral position in the patients mouth.

The magnitude of possible deviations caused by this sensitive procedure may have balanced the positive effects of the substituted manual procedures in the studies comprising this thesis.

### **Planning of implant positions**

The digital planning procedure is initiated after the digital files are imported, segmented and aligned in the planning software. The implant position is decided based on an ideal relation to the planned prosthetic restorations and the local anatomy.

#### **The ideal implant position:**

The three-dimensional position of the implant in relation to the surrounding anatomical structures as well as the prosthetic restoration is important for the result. The planning process in the guided surgery software makes it possible to optimize the implant position to avoid technical and biological complications. The ideal implant position aims at preserving the bundle bone as well as an adequate blood supply to the surrounding tissues. The implant body was placed leaving 1.5 - 2mm buccal bone (39). The implant was placed leaving 1.5 mm to a neighboring tooth and 3 mm if the implant was next to another implant. The measurements are derived from the expected remodeling of the proximal bone (174). Care was taken to embed the implant body in bone as the included studies used bone level implants. The coronal part of the implant was placed 3-4mm below the expected mucosal margin of the planned implant crown (175). The coronal part of the implant was planned to be 1.5 – 2mm palatal to the incisal margins. This is especially important in the esthetic area (176). There are studies pointing out the importance of an optimal implant position for the esthetic result (177). The implant angulation was planned to achieve a screw retained

restoration: The center line of the implant body was placed palatal to the incisal margin or on the occlusal surface.

The possibility to review the planned prosthetic restorations ahead of implant installation made it possible to design restorations considering estimated biomechanical loading of the implant retained restorations. The consequences of overloading implants remain unclear (178-181), but an increased incidence of mechanical complications may be anticipated as seen with cantilever prostheses.

The optimal positioning of the implant will in some cases need to be revised according to the available alveolar bone and other anatomical structures.

The implant planning software used in studies No 1, 2 and 3 had a line around the virtually planned implants indicating a safety zone. The safety zone is an indication of how close one may place the implant in relation to other anatomical structures and comprise the margin of error in guided implant surgery. Several review studies have been performed to evaluate the accuracy (3, 28, 91, 134, 142, 151, 152). Van Assche and coworkers did a meta-analysis and found a mean error of 1.0mm (95% CI 0.7 – 1.3mm) at the entry point and 1.4mm (95% CI 1.1 – 1.7mm) at the apex with a mean angular deviation of 4.2 degrees (95% CI 3.6 – 5.0 degrees) when analyzing in vivo studies. The results from the included studies in this thesis emphasize the importance of respecting a 2-3 mm safety zone as this will comprise the expected possible deviation related to template guided implant surgery. Of the 85 implants included in this thesis only two had a metric deviation exceeding 3 mm, while the majority had a deviation of 1-2mm. Extending the common safety margin of 1-2mm to a 2-3 mm margin will reduce complications related to implants violating anatomical structures further. Scientific evidence defining the when the level of inaccuracy becomes unacceptable has yet to be defined (182).

A recent study points out that the “ideal” implant position is not unambiguous but exists within a range of clinically suitable positions allowing for a screw retained restoration (145).

### **Surgical guide design**

The surgical guide was designed by the prosthodontist in study No.3.

A virtual sleeve was generated after the implant was positioned in the software. There was in some instances inadequate space between teeth to secure the sleeve completely in the guide body. This may result in sleeve loosening and introduce inaccuracies in the procedure. The sleeve position had to be adjusted to avoid interferences between the sleeve and bone or teeth. The software calculated the distance from the top of the planned implant to the sleeve, which in turn was positioned into the virtual surgical guide to create control over depth. It was important to keep the distance as short as possible as deviations will increase with the length between the sleeve and tip of the bur (136, 137, 183).

The guide body was designed after the sleeve position was determined.

A path of insertion was set to allow a complete and stable intraoral installation of the guide. An incorrect path of insertion may affect the possibility to seat the guide completely on all teeth. It was furthermore important to design a guide with an adequate tripod design for stability. It was as well important to obtain adequate material thickness to withstand the rotational forces applied on the guide during osteotomy and implant installation.

Dislodgement, guide fracture or sleeve loosening may impede the accuracy of the procedure.

The virtual guide was positioned onto the surface scan copying the outer surfaces of the dentition as the inner surfaces of the guide. The guided implant software determined an offset (distance) between the two surfaces to allow the guide to be fully seated onto the supporting

surfaces. The identical position of the guide in the planning software and intraorally in the patient is of utmost importance to the accuracy of the procedure. Deviations will imply differences between the planned and achieved implant positions as a mispositioned guide will lead the implant into a different position.

This may have had implications for the results in the present thesis.

The templates in this thesis were designed by the dental technician in study No 1, by the manufacturer in study No 2 and by the prosthodontist in study No 3. A possible downside of giving the implant team a total control over the complete process (as in study No 3) is the absence of an external quality assurance. External quality assurance where trained specialists verify the design process and template production may probably yield lower deviations.

Guided implant surgery systems, without the added security of an external quality assurance, will probably demand a thorough training of the system operators.

### **Surgical guide production**

The surgical templates in study No 1 were produced in a dental laboratory using traditional materials such as wax, plaster and acrylic. The materials and their handling are well known to dental technicians. Production discrepancies are easily revealed as a conventional plaster cast is used as a starting point. The production included several labor-intensive procedures and were expensive. Elimination of some of the manual working procedures were tested in study No 2 and 3.

Surgical guides were produced in a stereolithographic process in study No 2 and 3.

Stereolithography is an additive method of 3D printing that utilizes a laser and liquid resin offering good accuracy, resolution, and a smooth surface finish (184-186). The process is able to produce complex 3D objects based on standard tessellation language (.stl) files.



The surgical guides were designed in the guided implant software and exported as .stl file for production. None of the surgical guides in the included studies in this thesis were produced by the restorative team. There are, however, known deviations associated with stereolithographic production which may have affected the surgical guides used in the studies. The .stl file describing the guide bodies was imported into an additive manufacturing software (CAM) to prepare the file for the printing process.

Pre-programmed CAD/CAM software prepared the object by slicing it in layers before was sent to the stereolithographic building machine. The stereolithographic machine had a laser aimed at the resin imaging each layer in the building process. The object was built layer by layer onto the building plate as the laser cured the resin. The process was repeated until the object was complete. Layer thickness may have affected the trueness of the guides (187).

Photocuring of the polymers may as well have induced polymerization shrinkage in the surgical guides (188) affecting their trueness. Post processing is an important step in the stereolithographic production and is important to achieve the optimal mechanical properties. Improper handling and procedures may prevent a correct reproduction of the object (189, 190).

There are several studies documenting the accuracy and precision of stereolithographic production (191-194). The studies are difficult to compare due to methodological differences. Operation of stereolithographic machines, building processes and post processes are complicated and demands trained personnel to achieve optimal results as demonstrated by Sommacal and coworkers (195). The first scientific publications yielding promising results are emerging to document this type of production, but more documentation is needed (196, 197). Winder and Bibb discussed state-of-the-art software and hardware for medical rapid prototyping in their publication. They illustrated several limitations to the stereolithographic production processes and a range of unwanted artefacts that may affect the result. They

concluded that the production process must be subjected to a rigorous quality assurance system controlling every step of the process (198). A recent interesting research focus is the position of the object on the building plate in the stereolithographic printer. Authors have recommended an optimal printing direction to achieve maximal dimensional accuracy (189, 190, 199). The selection of a build direction will affect the slicing of the object used by the printer in the printing process resulting in a “z-stepping” effect on the surface of the surgical guide. The effect is dependent on the object geometry, layer thickness, build direction and printer machine. Optimizing the build direction and layer thickness may minimize this effect. Dental technicians and system engineers will possess extensive competence in separate parts of the guided implant surgery workflow. System engineers handling sensitive operations as segmentation, superimposition as well as the stereolithographic production may lower the total deviation of the procedure. A well-trained dental technician will have knowledge on the application of advanced dental materials used in guided implant surgery as well as implant prosthodontics. The exclusion of such skilled personnel, as in study No 3, implicates that the treatment team needs to possess an extensive understanding of technical limitations in the guided implant planning and execution.

Quality assurance by external qualified personnel were excluded in study No 3. The software yielded an .stl file after the planning phase. The open file format made it possible to produce the surgical guides at any given production facility chosen by the restorative team. This had the potential to reduce associated cost without decreasing the accuracy of the procedure (200). As the cost of smaller 3D printers has decreased, the restorative team may choose to produce the guides in the dental office (200, 201).

Stereolithographic production may, as stated above, introduce deviations in the guided implant procedure. The different printing processes, as well as data from the IO scan and subsequent superimposition, may affect the surgical guide where the guide does not obtain the

similar position in the patients mouth as in the planning software. This may introduce clinically significant deviations. Deviations in the procedures related to the digital planning and production of surgical guides may result in a difference between the position of the surgical guide in the planning software and intraorally in the patient.

This is probably a major contributor to the results observed in this thesis.

### **Execution of template guided implant surgery**

Surgeons have for many years used different aids for the transfer of the surgical plan to the actual surgical instance. The Preston clear splint is an example of such an aide (33). Surgical stents are in use today but suffer under a low accuracy. Farley and coworkers compared modern guided surgical templates with the surgical stents and found the computer guided surgical templates to be superior (202).

The guided implant surgical procedure may implicate errors contributing to a deviation from an ideal treatment results. Several complicated technical procedures are performed by the surgeon. The surgeons experience is explored in a recent study by Fernandez-Gil and coworkers (133). The group found that experienced surgeons had significantly less angle deviations compared to novice surgeons. The finding is supported by Cassetta and coworkers which as well pointed out that there is a learning curve associated with the procedures. Marei and coworkers confirmed the effect resulting from the surgeon's experience (203). Our results do not support this finding. The same surgeon performed the surgeries in study No 2 and 3 in this thesis. The mean angle deviation increased from 3.33 degrees in study No 2 to 3.85 degrees in study No 3. There are probably additional factors affecting the angle deviations besides the operator experience. Inaccurate positioning of the guide in the mouth due to

factors as improper flap elevation, resilience of supporting structures or a mispositioned guide may result in deviations.

Other reasons for a mispositioning of the guide may be the technological limitations when using IO scans as the basis for adaptation. The superimposition of the IO scan onto the volume rendered 3D model from the CBCT as well as the stereolithographic planning and production of the guides. Cassetta and coworkers explored the consequences of a guide positioning error on the deviations between the planned and achieved implant positions on mucosal supported guides (135).

They found that a mispositioning of the guide could induce significant differences in the global coronal deviation. The study is not directly comparable to the present thesis as our studies used tooth supported guides but emphasize the importance of the identical positioning of the surgical guide in the virtual and the clinical situation.

Application of excess force on the guide and burs may cause deviations related to the tolerance between burs and sleeves. This intrinsic problem is adequately described by Cassetta and coworkers (135), Leaderach and coworkers and Koop and coworkers (137).

There must be a difference in diameter between the sleeve and bur to avoid excessive friction and dislodgement of the guide. The included studies in this thesis used a single guide system where keys and sleeves were used to accommodate different drill diameters in one guide. Two different systems were used: One system had sleeves mounted on the drill (Study No 2) and the other system used forks to accommodate the different drills in the guide (Study No 1 and No 3).

Our results indicate that the fork system yielded least deviations considering the angle and global coronal deviations.

Valente and coworkers discussed the intrinsic problem related to the sleeve and fork systems in detail (106). They concluded that 62 % of the total deviation in the guided implant

procedure is contributable to the intrinsic error. The tolerance may contribute significantly to a deviation if the surgeon is not aware of this potential problem. A simplification of the surgical procedure is probably an advantage and may contribute to lower deviations.

Optimization of the key, bur, and sleeve system without increasing the frictional forces are important. Further studies are required to assess the optimal component dimensions to reduce the deviations related to the mechanical components.

Most systems use a sleeve which is 5 mm in height. An increase in sleeve height would increase the accuracy but would be more difficult to use due to the limitation in mouth opening.

Another important aspect for a successful result is the position of the sleeve in relation to the marginal bone. The deviation related to the tolerance between bur and sleeve will increase as distance between sleeve and bone increases (204). Operators should therefore place the sleeve as close to the bone as possible without creating interference with mucosa or bone. The distance could be determined by the restorative team in study No 1. The distance was determined by the manufacturer in study No 2 while the software would not allow any adjustments in the distance in study No 3.

Heat generation during the osteotomy preparation is a well described problem in implant surgery (205, 206). Preservation of bone cells is vital to the healing process taking place around a newly installed implant, but cell death and bone necrosis are likely to happen if the temperature increases above 47 degrees for one minute. Careful osteotomy preparation procedure as well as cooling with saline is thus important to maintain a healthy bone tissue surrounding the dental implant. Cooling of the bone and burs with saline water is more complicated when using guided implant surgery as the guide body interfere with the water spray (207). (206). Care should thus be taken to avoid excessive heat generation during the drilling sequence.

The most obvious way of preventing complications associated with the surgical procedures is to simplify these as much as possible. This will result in a less operator dependent procedure thus increasing patient safety and efficacy in routine clinical settings.

There is a need for practical training and understanding of the possible factors contributing to deviations. Furthermore, deviations seen during the clinical application of guided implant surgery needs to be considered during patient selection (208).

### **Evaluation procedures**

The accuracy of a computer guided surgical procedure is measured as a deviation in angle or location between the planned and achieved position of the implant. Procedural accuracy is important as dental implants often are inserted in close proximity to critical anatomical structures.

The present thesis includes three clinical studies. Metric differences were measured based on postoperative CBCT's of patients and plaster cast models as well as IO scanning.

Postoperative CBCT's of patients should be avoided due to the ionic load as the examinations provide no advantages for the patients (49). Study No 1 document the use of postoperative IO scanning to calculate the deviation between the planned and achieved implant positions. The use of this method is limited to partial reconstructions as there must be recognizable anatomy present to align the virtual models. Post-operative implant positions are registered based on scan bodies mounted onto the implants. This procedure is less dependent on operator experience. This was verified in study No 1 and confirmed in recent studies by Brandt and coworkers and Cristache and coworkers (209). Brandt and coworkers concluded that results

from a postoperative CBCT yielded less accurate results compared to the surface registration method. This was not observed in our study as both modalities gave similar results.

The evaluation procedure was based on extractions of a volume rendered 3D model from the pre- and post-operative tomographs in studies No 1 and 2.

Anatomical structures were used to verify alignment of the virtual models and the metric differences were calculated based on visible representations of the implants. The procedure is technically challenging to the operator and by itself prone to deviations. Patient movements in the tomographic acquisition and scattering effects may lower the accuracy (138).

### **Consequential errors – the accumulation of errors in the planning and execution of guided implant surgery**

The present thesis seeks to explore if the introduction of digital tools to reduce the number of manual procedures in guided implant surgery reduce the observed variations between planned and achieved implant positions. The measured deviations between the planned and achieved implant positions may be the result of smaller deviations in each step of the planning and execution of the different procedural steps. The thesis describes procedural deviations associated with human operations as well as deviations associated with software and machines. Further research is needed to explore the significance of each step and actions needed in order to increase the accuracy further. Figure 10 describes the associated risks with different processes, associated deviations, and possible preventive measures (figure 10).

### **Patient benefit from guided implant surgery**

The included studies in this thesis demonstrates the possibility to digitally plan and install dental implants with the use of a digitally designed and manufactured guide with a reasonable

accuracy. There are patient benefits associated with guided implant surgery. The increased patient security is evident as the implants may be placed in close vicinity of critical anatomical structures.

A more optimal placement of implants in relation to the prosthetic restorations will result in improved esthetics as well as simplified hygiene measures. The possibility for a screw retained restoration is as well an advantage that may justify the use of guided implant surgery (8). The patient benefit using a guided surgical procedure is especially evident in cases where there is a need for several implants in an esthetically important area as the anterior region in the upper jaw as the distance between the implants may be calculated exactly (109). Patients with challenging anatomy as limited alveolar bone or vital structures in the near vicinity may be treated with confidence considering the mean deviations associated with the procedures. The possibility to restore the implant immediately after installation is another significant patient benefit (5). The digital planning procedures gives the possibility to manufacture a temporary prosthetic restoration ahead of the surgical instance and deliver it at the time of surgery. The comfort of not having to use a temporary prosthesis is significant to many patients. Complex rehabilitations where patients miss multiple teeth in both jaws may experience a simplified clinical pathway when multiple data sources are combined in planning of implant installation, production of surgical guides and subsequent provisional and permanent prostheses (210).

## **Limitations**

There are significant limitations related to the included studies in this thesis. The results should therefore be interpreted with caution.



The number of included patients is low. A power calculation was not performed ahead of the studies as there was a limited access to eligible patients within the inclusion criteria.

Planning procedures were performed in different guided implant surgery software.

Algorithms built into the software is not available for the investigative team for evaluation.

Implant planning and postoperative evaluation were based on computer tomographs from two different machines. Postoperative evaluation based on intraoral scans was based on two different intraoral scanners. There are publications stating differences between CBCT machines and IO scanners related to accuracy. Application of different machines will result in a limitation to the results.

Stereolithographic guides were produced on different printers in studies 2 and 3. The resin, settings in production software, building process as well as postproduction procedures may have influenced the achieved results and may thus limit the value of a direct comparison. The procedures were not available for evaluation. Calculation of metric differences between the planned and achieved implant positions were computed in three different metrology software. The algorithms performing the calculations are proprietary to the software companies and hence not available for the research group for validation. This is as well a limitation to the results.

The statistics in the three studies were calculated on implant level. Several patients received two implants inserted by one surgical guide. A mispositioned guide may have a stronger effect statistically as a mispositioned guide will affect two implants.

## **Achieved results**

The three included studies in this thesis used metric deviations between the planned and achieved implant positions as outcome parameters.

Several studies have been published on guided implant surgery during the last 20 years. Most of these studies are, however, based on in vitro (models or cadavers) materials. The number of clinical studies on fully guided implant surgery are limited.

Diversity between the limited available in vivo studies due to different software, template manufacturing, number of guides, guide support, surgical techniques as well as measuring parameters / metrology software makes it difficult to compare the different publications. In a review study on the accuracy of guided implant surgery including 24 clinical and preclinical studies Tahmaseb and coworkers reported a total mean error of 1.12 mm at the coronal point (1530 implants) and 1.39 mm at the apex (1465 implants) (28). The results in the included studies in the present thesis are in line with the results reported by Tahmaseb and coworkers.

The inherent inaccuracies may be divided into deviations associated with the planning procedures and the deviations introduced by the execution of the surgical procedure.

Separate cases where the deviations between the planned and achieved positions supersedes the mean deviations are probably associated with the surgical execution. Cases where deviations are less and close to the mean results will probably mainly be associated with deviations related to the variability included in the operations necessary to perform the computer guided implant installation procedure.

The measured median deviations are significantly different in the three studies:

Study No 1 has a scan prosthesis following through the planning procedure and the prosthesis is later converted into the surgical guide. This will, supported by the fiducial markers, assure the identical position of the surgical guide in the planning software and patient.

Study No 2 and 3 rely on a stereolithographic process to transfer the position of the surgical guide the planning to execution.

Deviations in the necessary planning and production processes in study 2 and 3 will probably lead to the misposition of the surgical guide and the increase in the vertical deviations between the planned and achieved implant positions.

The surface scan, superimposition as well as the stereolithographic production process may contribute to the misposition of the surgical guide. The interquartile range for the global deviations was rather low. This will indicate that the superimposition of the surface scans onto the tomographic models is not the primary source of error as inaccuracies in the superimposition would lead to a larger spread in global deviations in all directions as the IO scan is not placed correctly onto the volumetric 3D model from the CBCT. The

superimposition will probably contribute to the total measured deviations but is probably of lesser importance compared to the production of surgical guides in studies two and three.

Median depth measurements for studies 2 and 3 reveal that the implants were placed higher than planned. There is reason to believe that the significant different dept measurements between study 1 and studies 2 and 3 were a result of differences in the position of the guide in the digital planning and intraorally at the surgical procedure.

The highly significant difference in median depth deviations between studies indicate that deviations related to the surface scans and the stereolithographic production are most important. The surface scans in study number 2 were performed by a desktop scanner where the trueness and precision are superior to the intraoral scanner applied in study number 3. The median depth deviation improved from study 2 to study 3 indicating that the surface scans had less impact on the results compared to the digital guide production process. Further research is needed to identify the significance these findings.

The common output parameters depth, angle and global metric differences were compared between the planned and the achieved implant positions in the three included studies. Median differences in depth, angle and global deviation at the apical point were statistically significant at  $p < 0.05$ .

The results support the null hypothesis.

### **Concluding remarks**

The aim of the present thesis was to explore if digitalization of manual procedures associated with tooth supported static guided implant surgery would increase the accuracy of the procedure. The hypothesis was tested in three prospective clinical trials. Specific manual operations were substituted by digital procedures in the studies. The surgical execution was identical. The primary measurement parameters were the differences between the planned and achieved implant positions. The three studies were compared by three common parameters: Depth, angle, and global differences between the planned and achieved implant positions. The measured parameters did not reveal any positive effect on accuracy when the manual procedures were substituted by digital counterparts. Any gain in accuracy by exclusion of manual procedures are probably masked by new deviational patterns associated with the digital procedures. The thesis points out geometric problems associated with intraoral scanning of sharp edges as well as the stereolithographic building process. It is possible that the intraoral scanning may contribute to the measured deviations, even though the thesis indicates the digital building of the guides as the primary source of error.

A fully digital workflow in guided implant surgery may offer advantages for patients as well as treatment teams. Further research should systematically evaluate deviational patterns in each step in the digital procedures as well as in the computers and software necessary to perform guided implant surgery to optimize treatment results. Changes related to surgical guide support on teeth could be interesting if the results from the present thesis is confirmed. A possible solution would be to avoid using areas on teeth with geometries that are difficult to describe with .stl files as support for the surgical guides. Other possible research areas could be improvements in the bur-sleeve system as the current sleeve systems have inherent deviational patterns. Improvements in computer tomograph algorithms may improve the quality of surface rendered 3D models and replace intraoral scans in tooth supported guided surgery. Optimization of computer tomograph algorithms to have automatic segmentation of anatomic structures could as well increase patient security. Further guided software developments could use such automated segmentations to propose ideal implant positions for the treatment team.

Further systematic research is needed to reject the null hypothesis in the present thesis.

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# **Influence of digital design and fabrication of surgical guides on the accuracy of implant placement**

## **Legends**

### **Figure 1**

Static template guided implant surgery may be divided in three different categories according to the primary supporting structures on which the surgical templates are positioned: Mucosa (1), teeth (2) or bone (3).

### **Figure 2:**

The stereolithographic production process consists of several steps. The figure illustrates the different steps in the production process. All steps may affect the trueness of the surgical guide compared to the computer designed guide in the guided surgery software.

### **Figure 3:**

The figure illustrates the parameters describing the metric differences between the planned and achieved implant positions after guided implant surgery. The metric differences are calculated based on the different points position in a 3-dimensional environment.

### **Figure 4:**

Figure describing the parameters and nomenclature used for horizontal deviations in study No 1. Coordinates of the implants apical and coronal points were defined and used for the calculation of the metric differences. The 3D offset was defined as the 3D distance between the coronal centers of the corresponding planned and placed implants.

**Figure 5:**

Figure describing the parameters and nomenclature used for vertical deviations in study No 1. Coordinates of the implants apical and coronal points were defined and used for the calculation of the metric differences.

**Figure 6:**

Figure describing the parameters and nomenclature used for horizontal deviations in study No 2. Global deviation was defined as the metric distance between the coronal/apical centers of the implants.

**Figure 7:**

Figure describing the parameters and nomenclature used for vertical deviations in study No 2. Depth deviation was calculated as the distance between the coronal (or apical) center of the planned implant and the intersection point of the longitudinal axis of the planned implant with a plane running through the coronal (or apical) center of the placed implant parallel to the reference plane.

**Figure 8:**

Figure describing the parameters and nomenclature used for deviations in study No 3. The following parameters were calculated:

Global difference between the coronal and apical centers of the planned and achieved implant positions, angular difference between the longitudinal axes of the planned and achieved implant positions, and the depth difference measured at the coronal center of the planned and achieved implant positions.

**Figure 9:**

Figure describing the differences in the planning procedures in the included studies in this thesis. The colours describe the different participants involved in the planning, production and execution of guided implant surgery in the present thesis.

**Figure 10:**

Figure describing associated risks with different processes in static guided implant surgery, associated deviations and possible preventive measures.

**Table 1:**

Table showing results from all included studies on implant level.

Normality of continuous variables was tested by Shapiro–Wilk test and histogram.

Due to the low sample size and non-normal distribution of the continuous variables (depth coronal, angle, global coronal, global apex) Kruskal–Wallis ANOVA was used to detect median differences of continuous, numerical variables between the three groups (study 1, 2, 3), while Dunn's test for pairwise multiple-comparison.

Depth coronal, angle and global apex showed significant median differences between the studies. All differences were considered significant at  $p < 0.05$ .

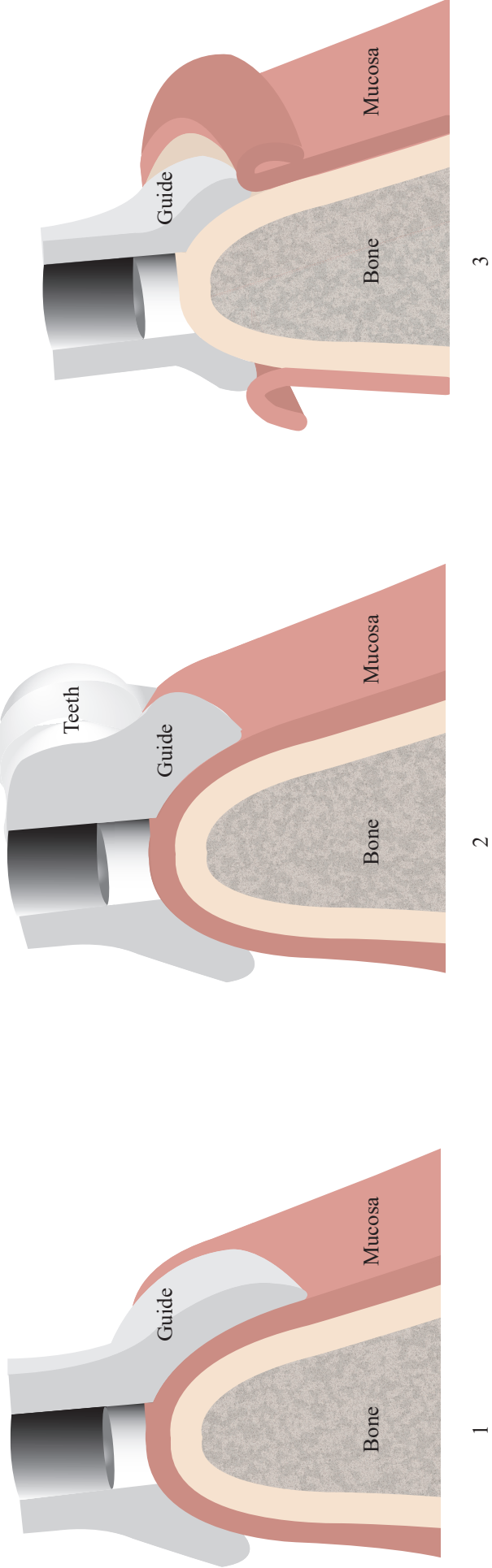


Figure 1

Figure 2

# Stereolithographic production process

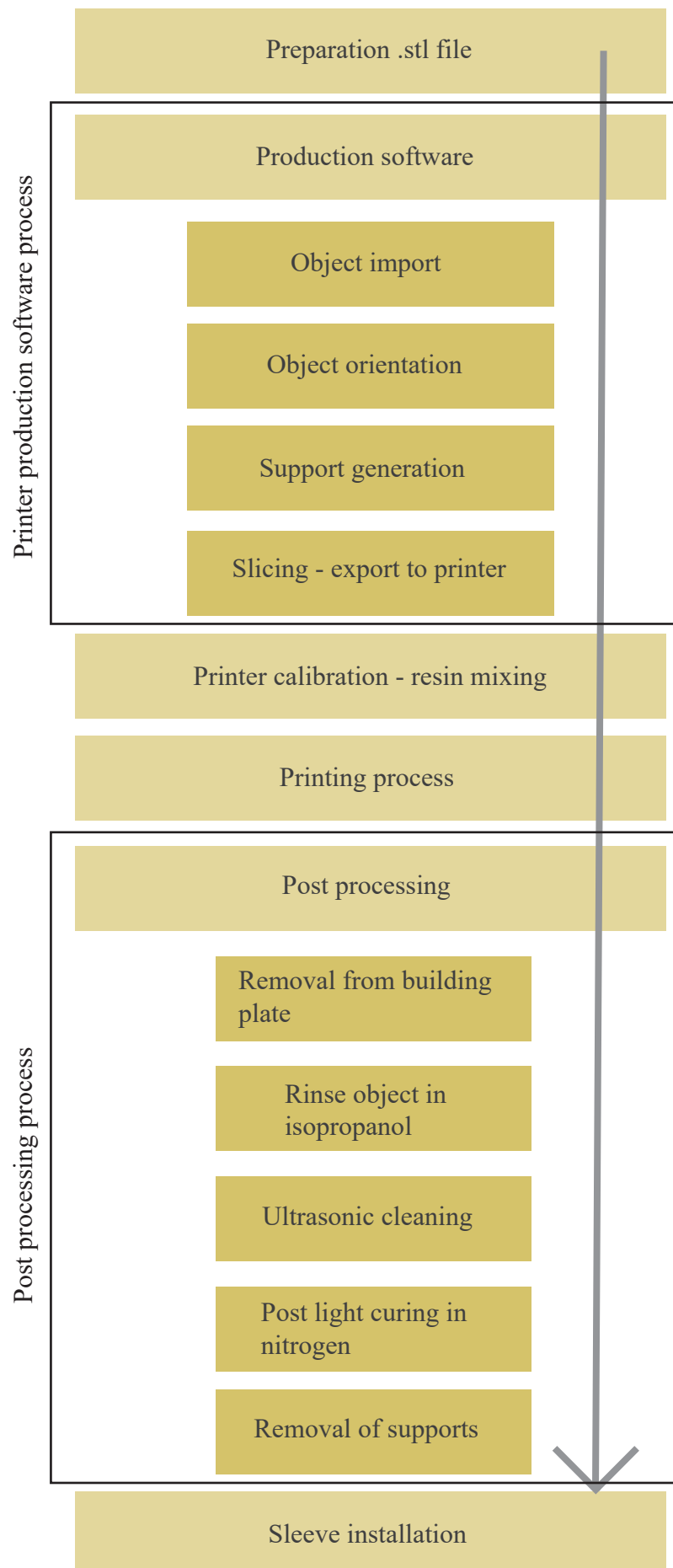


Figure 3

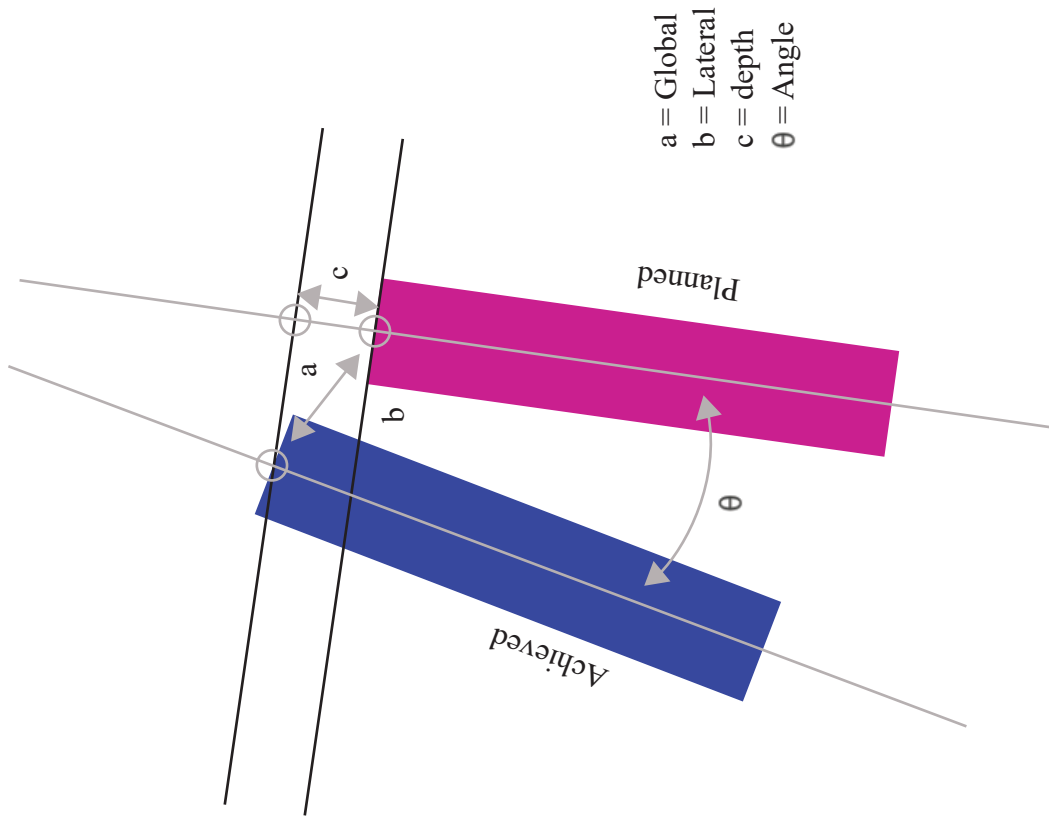


Figure 4

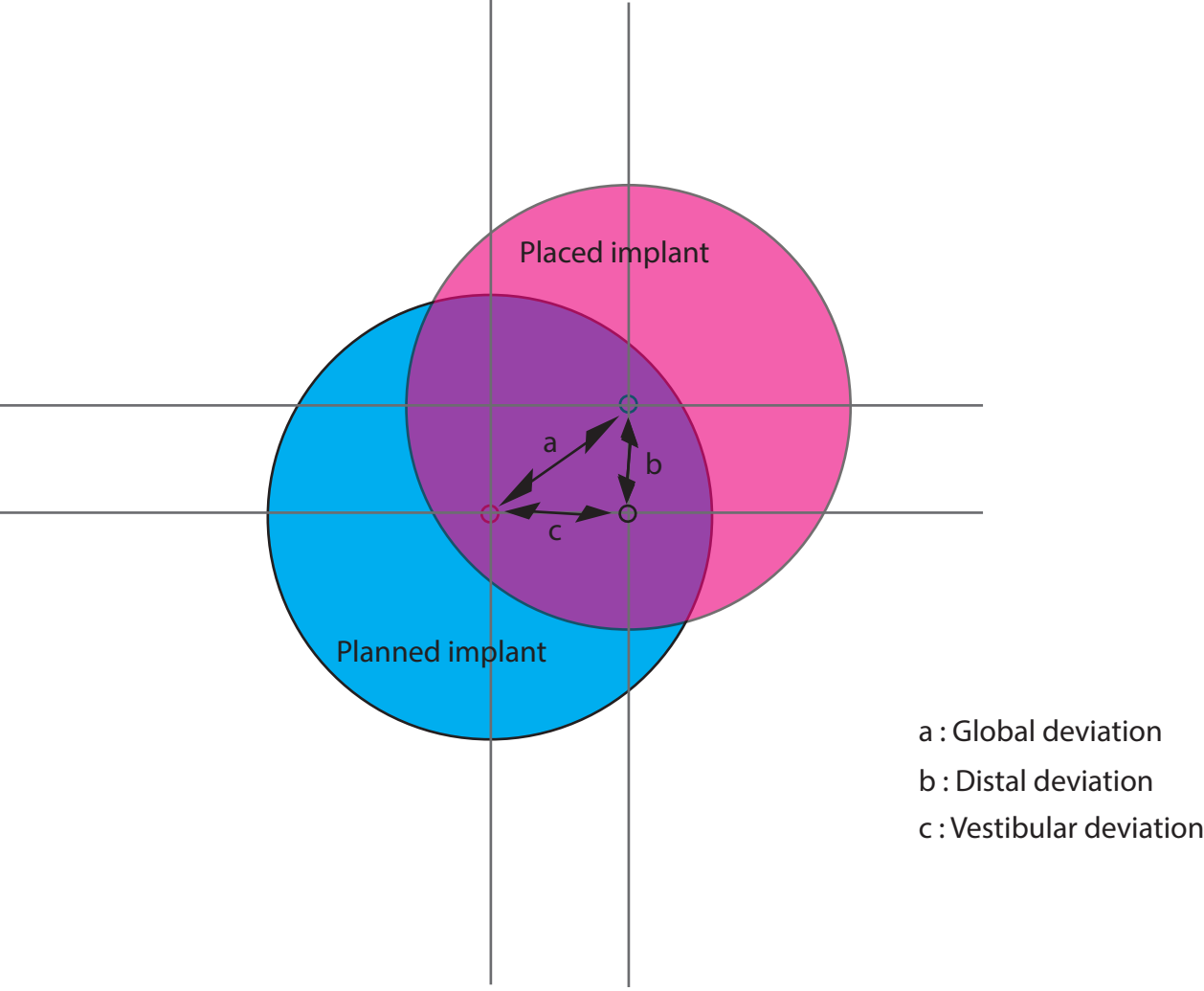


Figure 5

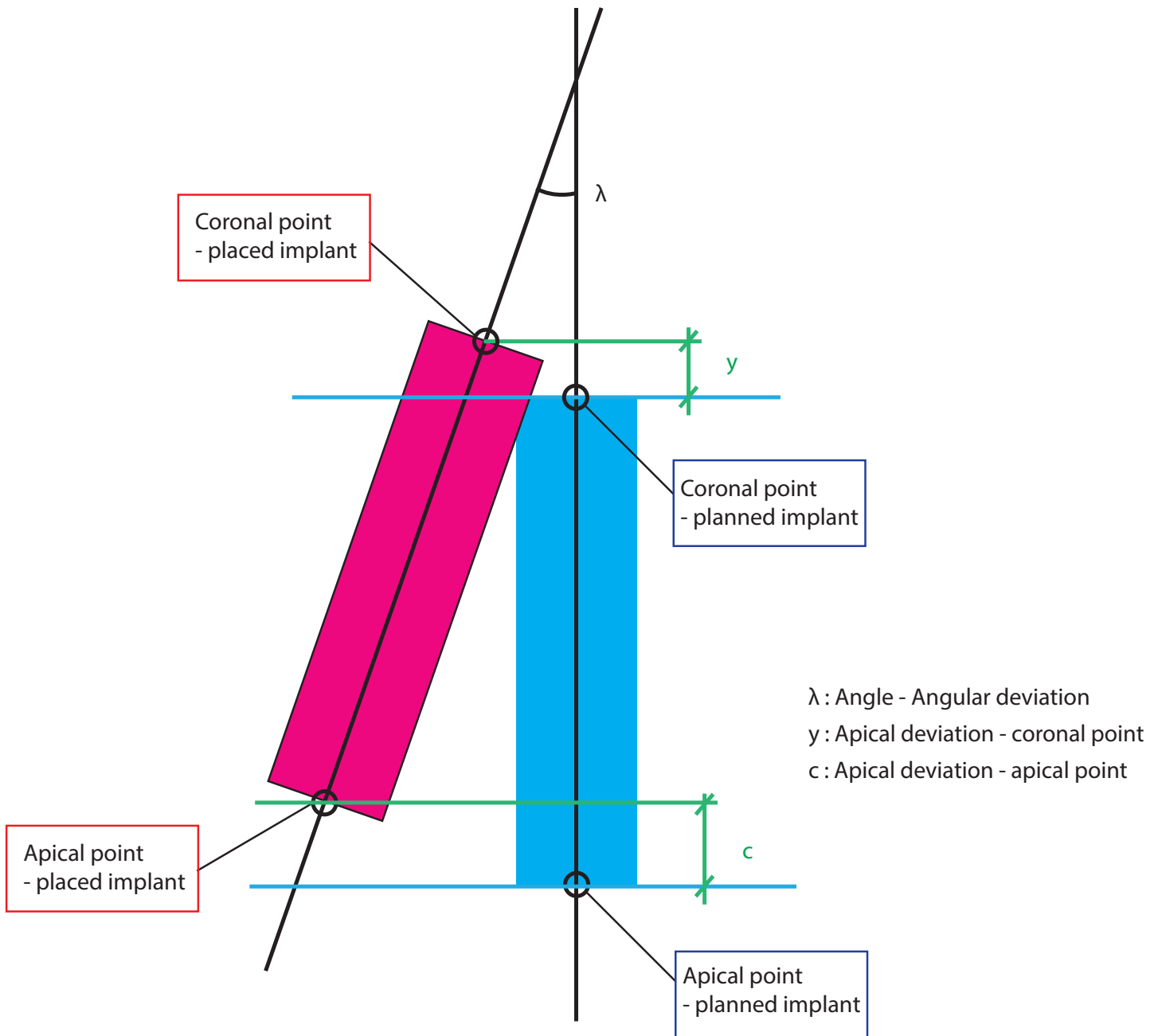




Figure 6

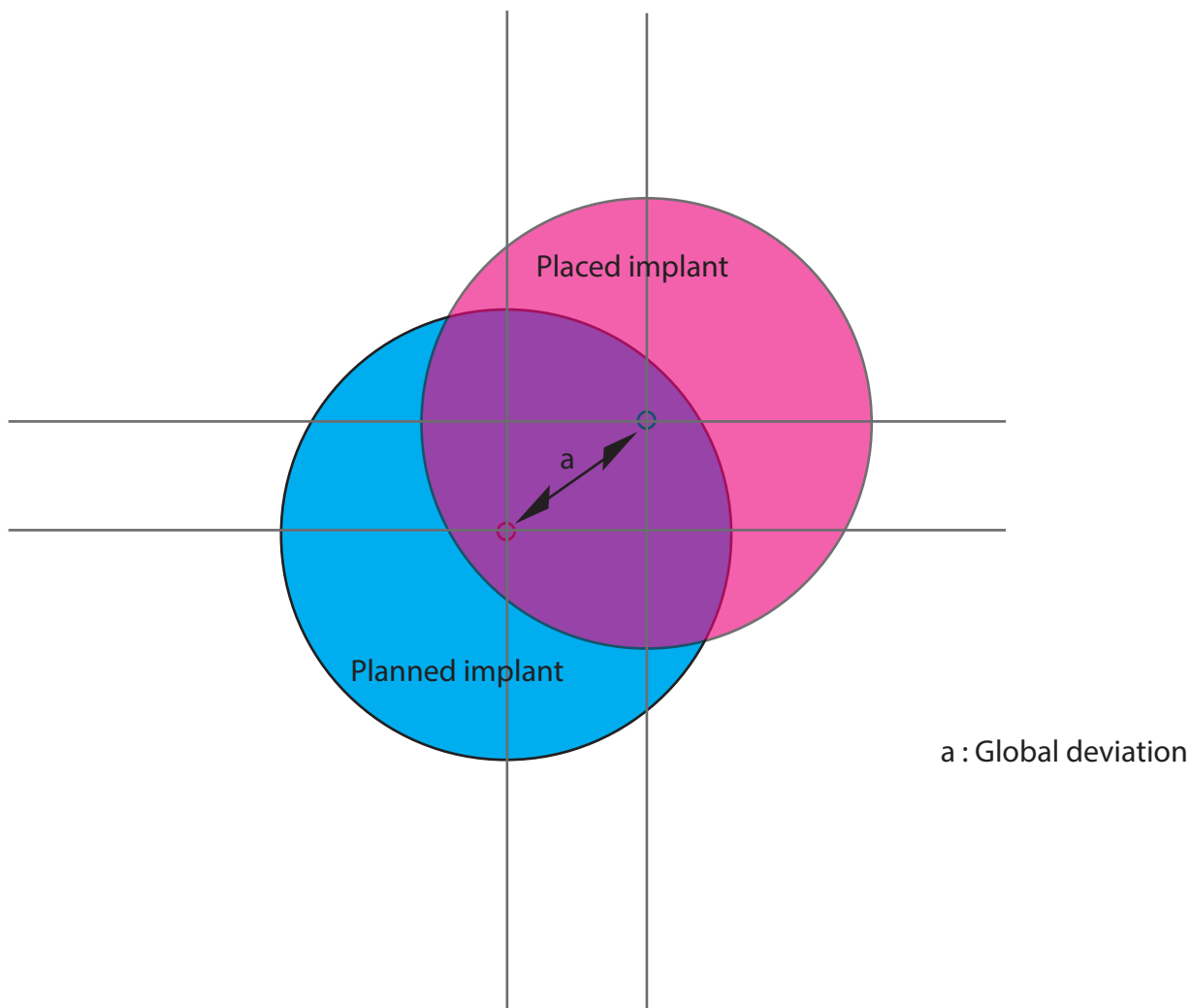


Figure 7

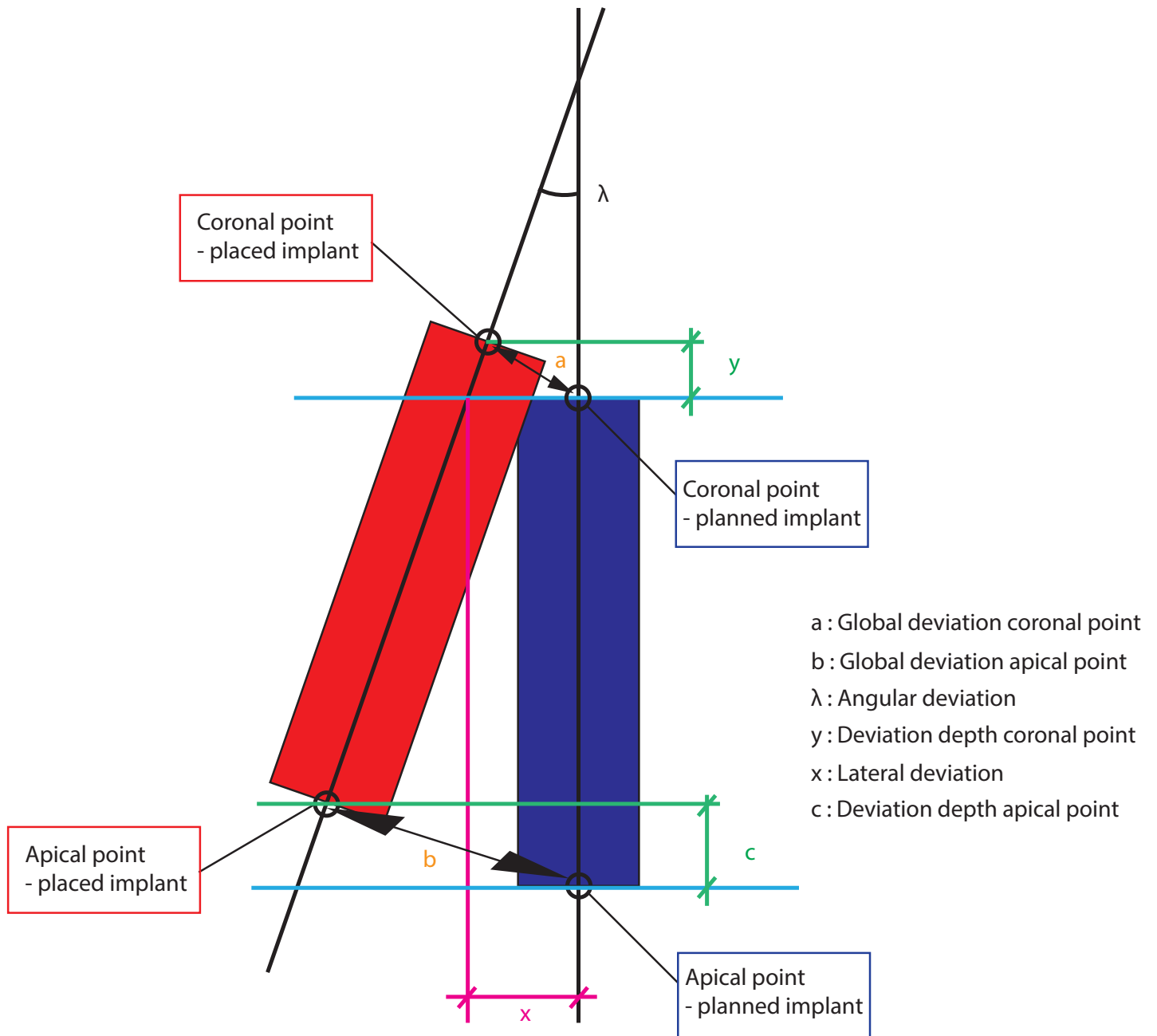


Figure 8

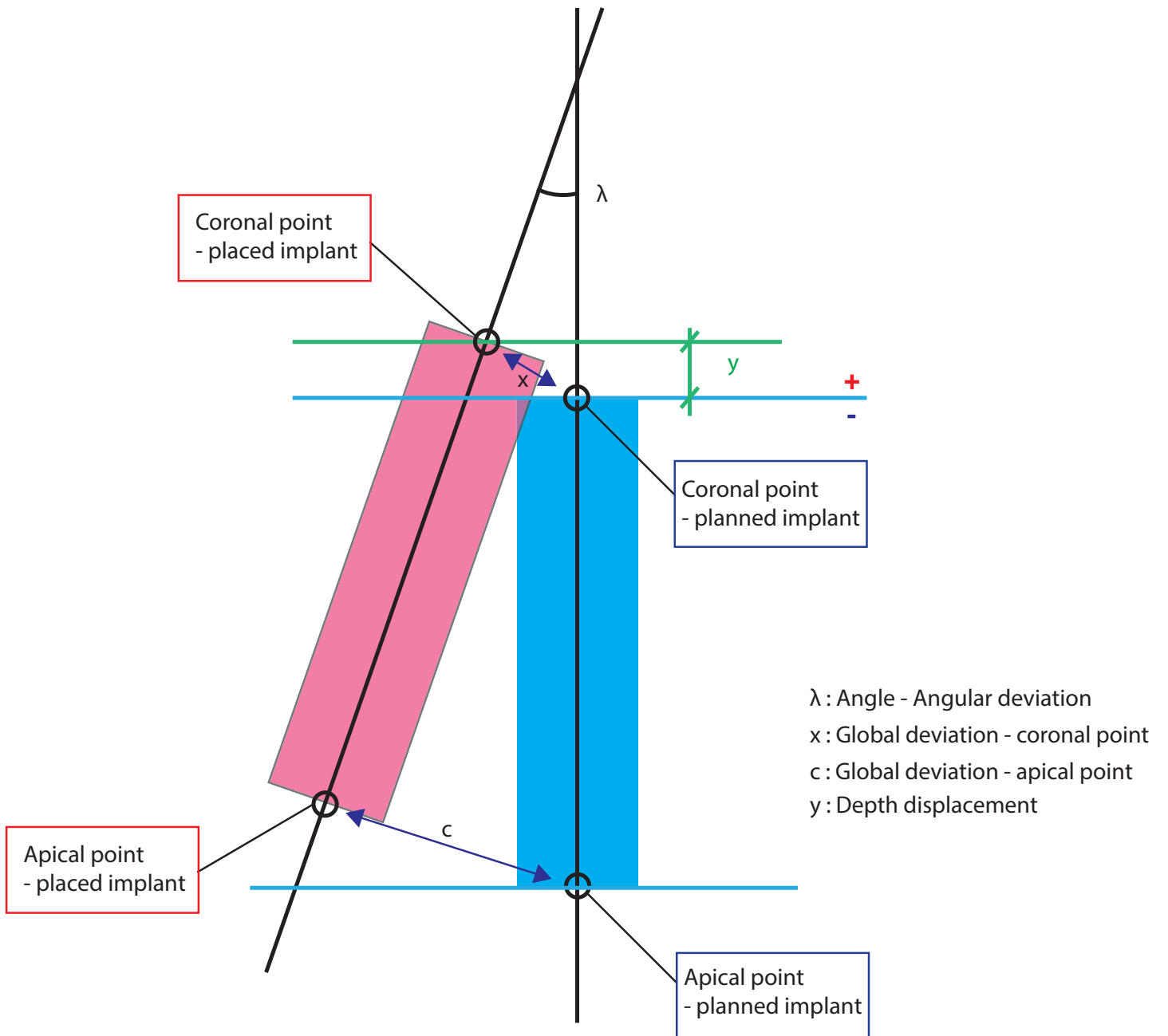


Figure 9

## Workflow - included studies

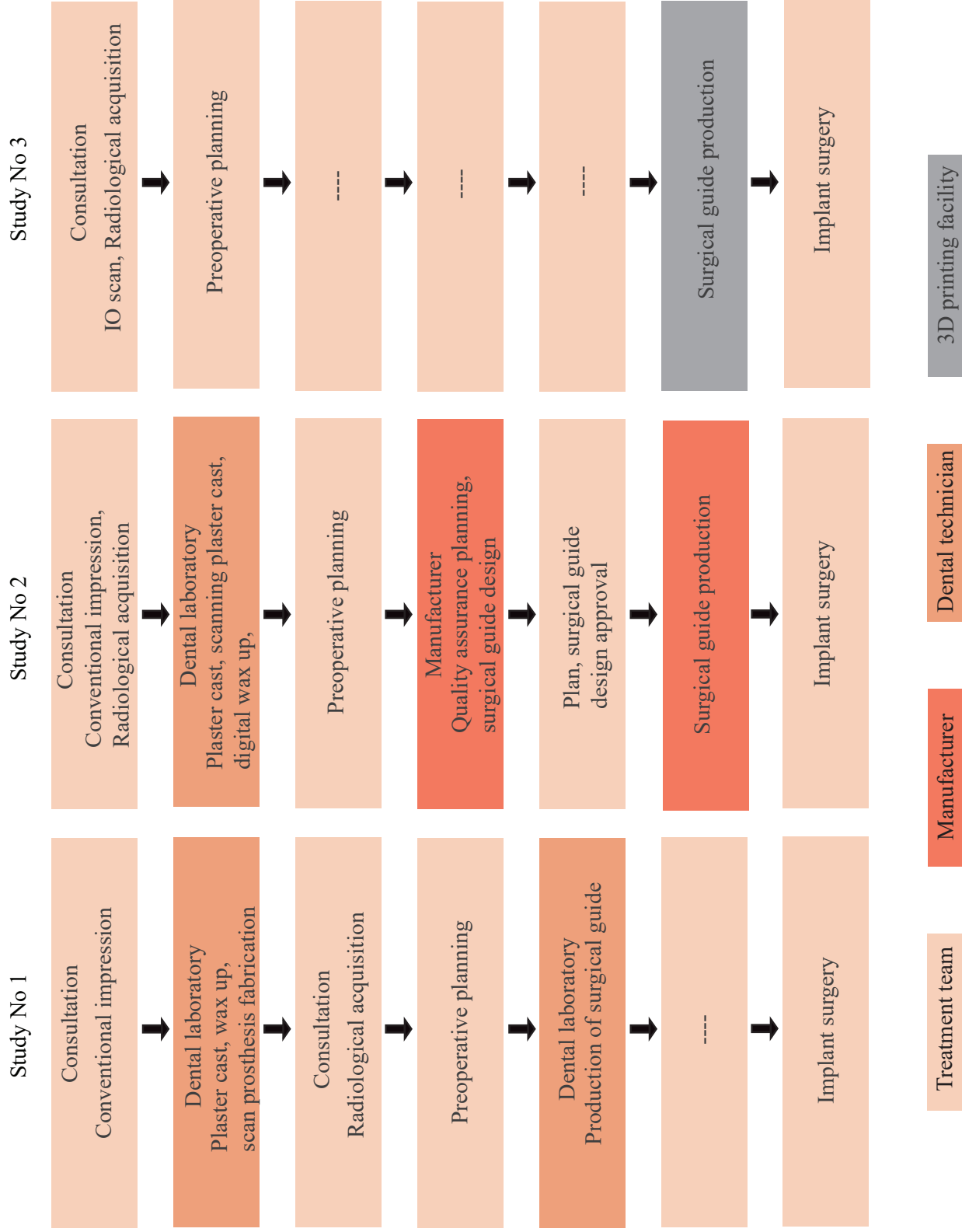


Figure 10 Static guided implant surgery: procedural risks and management

Process	Deviation	Prevention
Intraoral scanning	Dimensional inaccuracies	Correct scanning strategies Awareness of problems associated with sharp edges and full arch scans
Cone beam computed tomography	Dimensional inaccuracies Poor image quality (artifacts)	Avoid patient movement Experienced operator / review images for signs of movement Remove objects that may create artifacts
Guided surgery software	Inadequate implant positioning Inadequate superimposition procedure	Operator experience / training Operator understanding limitations / accuracy levels of software
Surgical guide design	Improper fit to supporting structure Guide fracture Difficulties associated with guide type	Operator experience / training / understanding of limiting factors (Offset, material dimensioning, sleeve distance from bone, inspection holes)
Surgical guide manufacturing	Implant deviation Dimensional inaccuracies	Operator experience / training / understanding of limiting factors (Building process / post processing)
Surgical guide stabilization / positioning	Improper positioning Guide movement during procedure	Operator experience / training / understanding of limiting factors (guide fixation, seating of guide, wobbling)
Anatomic location	Inadequate space for guide / components for drilling	Proper pretreatment assessment
Drilling / drilling components	Improper drill use Drill wear Inadequate irrigation	Avoid eccentric drilling Frequent replacement of drills and keys Copious irrigation
Operator experience	Poor knowledge and understanding of processes and limitations. Inability to identify risks	Advanced training and surgical skills before using guided implant surgery

Table 1

	Depth (Coronal)			Angle			Global (Coronal)			Global (Apex)		
	Study 1	Study 2	Study 3	Study 1	Study 2	Study 3	Study 1	Study 2	Study 3	Study 1	Study 2	Study 3
Median:	0.22	1.09	1.294	1.9	4.21	5.492	1.8	1.19	1.665	1.96	1.54	2.378
Interquartile range (IQR):	-0.68;0.24	0.53;1.23	0.16;0.71	1.6	1.08	2.859	0.9	0.90	1.681	1.11	1.03	2.244
Range:	-1.79;-1.13	0.25;1.88	-0.52;1.33	2.2	2.6	1.678	0.2	0.88	0.706	0.60	1.10	0.885
(Overall) P	0.0001***	0.0001***	0.0111*	10.6	0.84	5.572	1.0	1.63	1.794	2.10	1.61	2.668
P (between S1-S2)	0.000***	0.0002***	0.0014**	2	3.52	6.652	1.9	0.76	2.061	2.05	1.20	3.127
P (between S1-S3)	0.003***	0.003***	0.04*	2.5	5.42	1.899	0.9	1.23	0.680	1.08	2.02	0.676
P (between S2-S3)	0.003***	0.003***	0.04*	1.5	4.87	5.725	1.2	2.11	1.153	1.25	2.64	2.084
	-0.42	0.36	1.031	1.2	1.82	2.492	0.6	0.56	1.403	0.45	0.62	1.450
	-0.82	1.31	0.578	2.5	5.37	2.231	1.2	1.30	0.917	1.01	1.61	1.247
	0.56	1.11	0.392	0.9	1.53	4.008	0.8	1.38	0.952	0.79	1.54	1.580
	0.31	1.42	0.388	1.7	0.05	1.895	0.7	1.62	0.480	0.95	1.62	0.602
	0.24	1.54	1.182	1.7	2.79	5.729	1.1	1.56	1.518	1.25	1.68	2.302
	-0.17	1.66	0.601	5.9	6.04	8.599	0.7	1.68	1.572	1.38	1.91	3.355
	-0.70	0.43	-0.520	5.5	1.79	5.655	1.2	0.62	1.063	1.01	0.65	1.861
	0.32	0.25	0.292	2.2	1.21	2.592	0.9	0.73	0.443	1.23	0.92	0.738
	0.16	0.84	0.697	1.7	5.29	1.719	0.5	1.07	1.412	0.87	1.68	1.745
	-0.29	0.73	0.663	1.7	5.98	1.899	0.8	1.01	0.680	1.13	1.95	0.676
	-0.52	0.82	-0.166	0.7	2.81	3.785	1.2	0.86	0.474	1.30	1.08	1.119
	-0.06	0.32	0.244	1.9	3.06	3.410	0.7	0.59	0.713	1.07	1.04	1.172
	1.13	0.87	0.060	2.9	0.12	3.659	1.2	1.09	0.511	1.44	1.09	1.327
	0.00	0.93	0.512	2.4	4.71	3.837	0.0	1.00	0.794	0.44	1.49	1.326
	-0.43	0.52	0.089	2.6	2.74	3.213	0.5	0.70	0.356	0.86	1.06	0.801
	-0.49	1.34	0.113	1.6	3.47	2.607	0.5	1.34	0.653	0.64	1.52	0.964
	0.32	0.68	0.213	0.7	3.61	5.664	0.5	0.85	1.096	0.58	1.47	2.091
	-0.36	0.30	0.717	4.4	3.32	1.253	1.7	0.95	0.925	1.38	1.50	0.826
	-0.89	0.45	0.462	2.5	19.04	3.193	1.0	0.68	0.568	1.01	2.76	0.562
	1.21	0.45	-0.514	2.09	2.09	5.571	1.46	1.46	2.738	1.65	1.65	5.159
	0.98	0.98	-0.105	0	0	4.848	1.46	1.46	0.361	1.46	1.46	0.559
	1.23	1.23	0	3.91	3.91	0	1.51	1.51	0.361	1.51	1.51	0.559
	0.83	0.83	0	0	0	0	1.28	1.28	0.361	1.28	1.28	0.559
	0.99	0.99	0	0	0	0	1.33	1.33	0.361	1.33	1.33	0.559

Median:  
Interquartile range (IQR):  
Range:

(Overall) P  
P (between S1-S2)  
P (between S1-S3)  
P (between S2-S3)

\*\*\*p<0.001  
\*\* P<0.01  
\* P<0.05







## ORIGINAL RESEARCH

# Comparison of postoperative intraoral scan versus cone beam computerised tomography to measure accuracy of guided implant placement—A prospective clinical study

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**Abstract**

**Objective:** To evaluate the accuracy of implant placement with a digitally planned guided implant procedure. Two methods for identifying the actual postoperative positioning of the implants were compared: CBCT and IO scanning.

**Material and methods:** Twenty-eight implants with a sandblasted and acid-etched surface were placed in thirteen patients using tooth-supported surgical guides following a digital planning procedure. The implants were submerged for 12–15 weeks. New CBCT images were taken for identification of the implant position. After second stage surgery, scan bodies were mounted on the implants and scanned with an IO digital scanner. The recordings from the CBCT images and the IO scans were compared with respect to the identified positions of the implants.

**Results:** The study did not resolve any significant differences of the identified positioning of the implants as measured by CBCT or IO, except for the apical deviations at the coronal and apical points.

The angular difference between CBCT and IO scanning at the coronal point was  $-0.011 (\pm 0.6)$  degrees, whereas the 3D deviation was  $0.03 (\pm 0.17)$  mm. The distal deviation between CBCT and IO scanning was  $0.01 (\pm 0.16)$  mm, and the vestibular deviation  $0.033 (\pm 0.16)$  mm and the apical deviation difference was  $0.09 (\pm 0.16)$  mm. The 3D deviation at the apical point was  $0.04 (\pm 0.22)$  mm. The distal deviation between CBCT and IO scanning was  $0.06 (\pm 0.19)$  mm, and the vestibular deviation  $0.032 (\pm 0.23)$  mm and the apical deviation difference was  $0.09 (\pm 0.16)$  mm.

**Conclusion:** The study demonstrated that accuracy measurements using IO scanning yields comparable results to those obtained by CBCT.

**KEYWORDS**

clinical research, clinical trials, patient centered outcomes, surgical techniques

## 1 | INTRODUCTION

A long-term success of the esthetic and functional aspects of oral rehabilitation with the use of dental implants depends on an optimal three-dimensional positioning of the implants in the jaws. This will allow for favorable load transfer to the implant components and the bone and support for the soft tissue. The clinical procedures and materials used in dental implantology have thus continuously been developed during the last 20 years (Appendix S1; Albrektsson et al., 1988; Lekholm et al., 1999) to provide higher survival rates and improved esthetic results (Berglundh, Persson, & Klinge, 2002).

A thorough knowledge of the patient's anatomical structures is important for the implant surgeon when preparing for implant surgery. Conventional two-dimensional radiographs give limited objective information when the ideal positioning of the implants is to be decided (Wyatt & Pharoah, 1998). With the introduction of cone beam computed tomography (CBCT), a much more detailed treatment planning can be performed (Guerrero et al., 2006), (Loubele et al., 2008). The surgeon can obtain a complete, objective 3D overview (Brown, Scarfe, Scheetz, Silveira, & Farman, 2009) of the patient's bony structures from CBCT ahead of the surgical intervention with reasonably low exposure to radiation (Angelopoulos, Scarfe, & Farman, 2012; Loubele et al., 2009). When CBCT scans are combined with intraoral (IO) scanning and computer-assisted design and manufacturing (CAD-CAM), a more comprehensive 3D visualization of the bone structure can be made in the preoperative phase. This gives an improved treatment planning and consequently improved accuracy of implant placement (Katsoulis, Pazera, & Mericske-Stern, 2009; Lal, White, Morea, & Wright, 2006; Verstreken et al., 1996, 1998). Studies indicate that even experienced implant surgeons may observe improvements in implant placement accuracy using digitally planned surgical templates (Vermeulen, 2017). There are as well operator-dependent differences that affect the end results in implant surgery (Jemt, Olsson, Renouard, Stenport, & Friberg, 2016). Previous studies indicate that training in guided implant surgery procedures is necessary to successfully use this treatment modality.

Guided implant treatment applies a surgical guide to aid the surgeon in the ideal placement of dental implants. The guide is made based on computed tomographs and a manual or digital wax-up of the desired restorations. The bony structures and desired dental reconstructions are visible in dedicated software, and the surgeon can visualize the position of the planned implants in relation to the desired dental restorations and individual anatomy. The surgical guide is made based on the calculated coordinates of the planned implants and is manufactured in a dental laboratory or in a computer-assisted manufacturing system. The surgeon uses the guide to place the implants in their planned positions.

Deviations between the planned and achieved implant positions should be expected as a result of inaccuracies in the different procedures leading to the finished guide (Cassetta, Di Mambro, Giansanti, Stefanelli, & Cavallini, 2013). This discrepancy should be considered when applying the treatment modality clinically (D'Haese, Velde, Komiyama, Hultin, & Bruyn, 2012).

Identifying the achieved implant positions after surgery is of importance when evaluating planning and treatment procedures

for guided implant surgery and for evaluating the surgeon's manual performance. CBCT has been the dominant choice in scientific studies for identifying the achieved implant positions after surgery (Di Giacomo, Cury, Araujo, Sendyk, & Sendyk, 2005; Ersoy, Turkyilmaz, Ozan, & McGlumphy, 2008) although the use of CBCT will expose the patients to additional radiation. The use of intraoral scanning may be an alternative to CBCT for this purpose.

The aim of this study was to evaluate the accuracy of the placement of dental implants when using digitally designed tooth-supported surgical guides. Furthermore, it was the aim to evaluate whether the recording of postoperative implant positions with the use of IO scanning was comparable with the one achieved with the use of CBCT, giving basis for a possible use of IO scanning in further clinical scientific studies.

## 2 | MATERIALS AND METHODS

### 2.1 | Study design

The study was designed as a prospective clinical study to evaluate the *in vivo* accuracy of digital planning and placement of dental implants using surgical templates.

The study protocol was approved by the Regional committee for medical and health research ethics of Norway (REC South East protocol no. 2011/2568), and the study was prepared in accordance with the appropriate STROBE guidelines (von Elm et al., 2007).

### 2.2 | Patient screening and selection

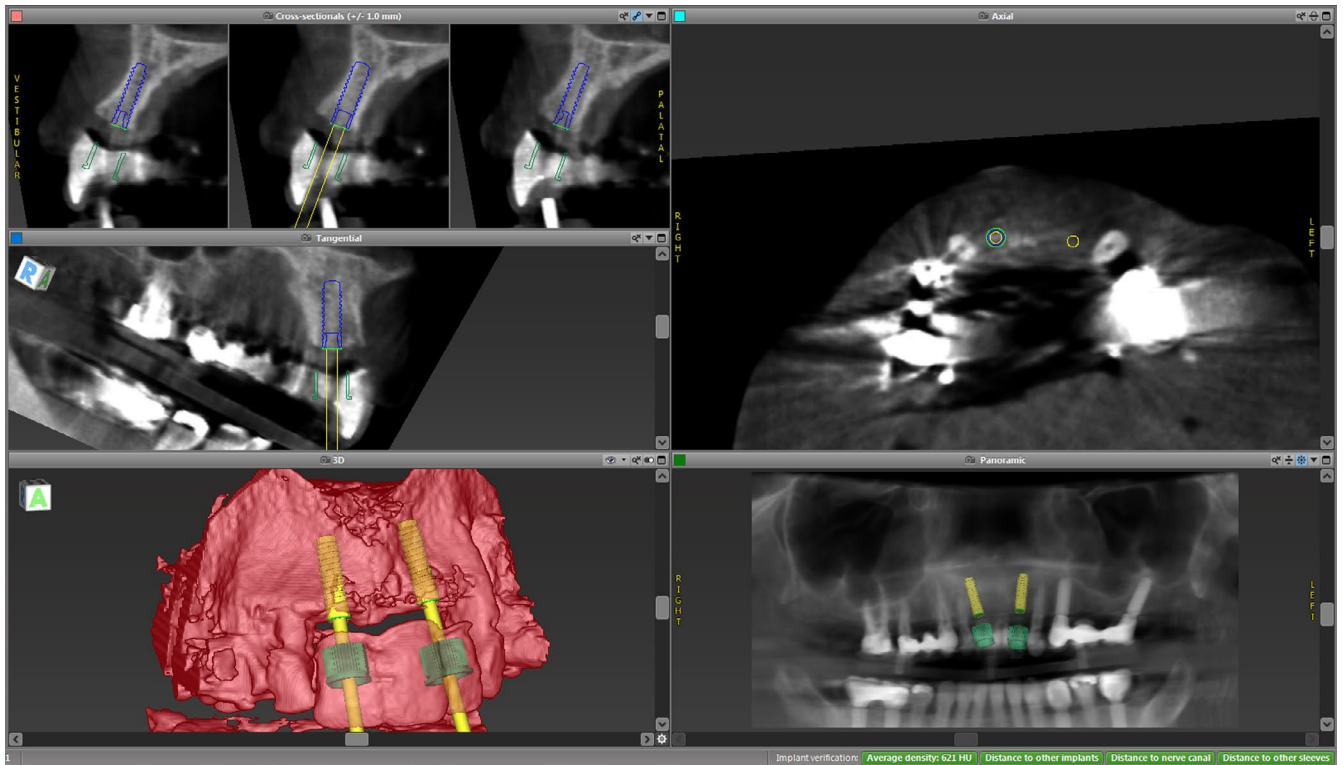
Study participants were recruited from patients referred to the Institute of Clinical Dentistry, University of Oslo, Norway during March to April 2012. The subjects had to be in good health, and their medical history was no constraint for undergoing dento-alveolar day surgery. The inclusion of the patients was limited to ASA class I and II (Doyle & Garmon, 2019).

The subjects included had to be over 18 years old, partially dentate and be candidates for partial reconstructions using dental implants. The subjects were further willing to undergo a two-stage surgical procedure.

Subjects presenting the following conditions were excluded from the study: (a) clinical and radiographic signs of untreated or active periodontal disease; (b) previous intake of bisphosphonates; (c) current use of systemic corticosteroids; (d) documented therapeutic radiation to the head and neck; (e) uncontrolled diabetes; (f) smoking habit; (g) pregnancy or lactating.

The patients had a preliminary consultation and clinical examination after initial selection. The number of referred and suitable patients determined the number of participants in the study. Potential candidates were given a written copy of the informed consent form and had the study protocol thoroughly explained to them.

Patients accepted for the study had to sign the informed consent form prior to inclusion and the patients had the right to withdraw from the study at any time during the study period. Patients



**FIGURE 1** The desired implant positions were planned based on the desired prosthetics and the available bone. Additional bone augmentation procedures may be planned ahead of the surgical procedure

who consented to the study were scheduled for a second examination that included a complete oral and radiological examination.

### 2.3 | Planning procedures

The prosthetic treatment planning was performed by a prosthodontist, and a manual wax-up was made by a dental technician.

A scanning template based on the wax-up was fabricated from acrylic resin containing 30% barium sulfate. A template (TempliX, Institut Straumann AG) containing three fiducial markers made from titanium was fused onto the scanning template.

The intraoral fit of the scanning template was verified before the computed tomographies were acquired.



**FIGURE 2** Planning of the abutments in relation to the desired implant position

Cone beam tomographies were acquired with a Soredex Scanora 3D (Soredex) with standard settings of 90 kV, 7 mAh and a voxel size of 0.125 mm. The tomographs were exported in DICOM format with a slice thickness and spacing of 0.25 mm.

The CBCT data were subsequently imported into the planning software (coDiagnostiX, Dental Wings Inc; Figure 1, Figure 2).

The implant positions were planned in relation to the optimal design of the prosthetic reconstruction. With multiplanar reformatting, it is possible to simultaneously view the dataset containing the bony structures, desired prosthetic reconstructions, and planned implants in the axial, coronal, and sagittal planes. The calculated positions of the planned implants were exported from the software.

A manual process converted the radiographic template into a surgical guide:

The dental technician remounted the scanning template into a special laboratory appliance (GonyX, IVS-Solutions). Holes were prepared in the guide after entering the coordinates of each virtually calculated implant position, and metal sleeves (Institut Straumann AG) were luted in the prepared holes. The guide sleeves were 5 mm in length and 5 mm in diameter.

### 2.4 | Surgical procedures

All surgical procedures were performed by one certified oral and maxillofacial surgeon (HOB). The surgeon had a limited experience in guided implant surgery prior to participating in the study. All patients received 600 mg of clindamycin 45 min preoperatively. Local

infiltration anesthesia with a vasoconstrictor (Xylocaine Dental with adrenaline™, Dentsply) was used during the surgical procedures.

Patients rinsed with chlorhexidine gluconate 0.2 mg/ml for 60 s (Corsodyl™, Glaxo Smith Kline) prior to initiation of surgery.

After verifying anesthesia, a supra-crestal incision without vertical releasing incision was performed before reflecting a mucoperiosteal flap. All implants were installed in healed sites.

The osteotomies were prepared according to the manufacturer's instructions (Institut Straumann AG) using the surgical guide with continuous sterile saline irrigation.

A guided implant (Bone Level, RC, guided, SLActive®, Institut Straumann AG) was then placed using the surgical guide. A closure screw was placed for the submerged healing of the implant.

Repositioning of the mucoperiosteal flap was performed using nonresorbable pseudo-monofilament sutures (Supramid®, B. Braun Melsungen AG). Ibuprofen (400 mg), and acetaminophen (500 mg) was prescribed for every 6 hr for the first 48 hr after surgery and thereafter as needed. The patients were instructed to use chlorhexidine gluconate 0.2 mg/ml mouth rinse twice daily for one week. Sutures were removed one week postoperatively. Oral hygiene was verified and reinstructed if needed.

A two-stage surgery procedure was followed, and all implants were thus submerged during the healing period of 12–15 weeks according to the standard regimen at the Faculty of Dentistry, University of Oslo. The implants were exposed into the oral cavity after a separate surgical procedure with mounting of a healing abutment.

## 2.5 | Prosthetic procedures

Prosthetic rehabilitation was initiated two weeks after the second stage of surgery. All implants were digitally scanned with the iTero IO scanner (Align Technologies) after the appropriate scan body (Institut Straumann AG) had been installed on the implants. A full-arch scan was performed (Figure 3).

Single unit crowns were manufactured based on the scan. Multiple implants in fixed partial denture (FPD) reconstructions were rehabilitated based on conventional impressions. Implant level impressions were taken with Impregum (3M ESPE) using the appropriate impression copings (Institut Straumann AG). Single implants were rehabilitated with individual titanium abutments and zirconia crowns. Fixed partial dentures were made on standard Straumann Multibase (Institut Straumann AG) abutments. All prosthetic reconstructions were screw-retained and placed with the correct torque according to the manufacturer's guide. One week following initial insertion, the torque was checked and screw channels were closed with 3M ESPE Z250 (3M ESPE). All patients received thorough instructions for proper oral hygiene measures.

## 2.6 | Verification protocol—accuracy

The metric deviations between the planned and achieved implant positions in this study are described with the ordinarily used terms to give orientation within the oral cavity. Vestibular–oral, mesial–distal, and apical were used to describe the direction of the metric differences. Coordinates of their respective apical and coronal points were defined



**FIGURE 3** The achieved implant position was registered based on an intraoral scan of scan bodies installed on the implants

and used for the calculations. Differences in angulation were as well calculated based on the 3D angle between the longitudinal axis of the planned and placed implants. A 3D offset value was calculated. The 3D offset was defined as the 3D distance between the coronal centers of the corresponding planned and placed implants (Figures 4,5).

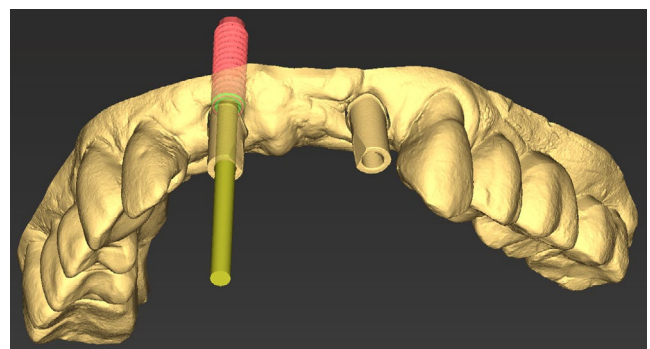
### 2.6.1 | IO scanning

All implants were scanned with the iTero IO scanner after the appropriate scan bodies (Straumann) were installed on the implants (Figure 6).

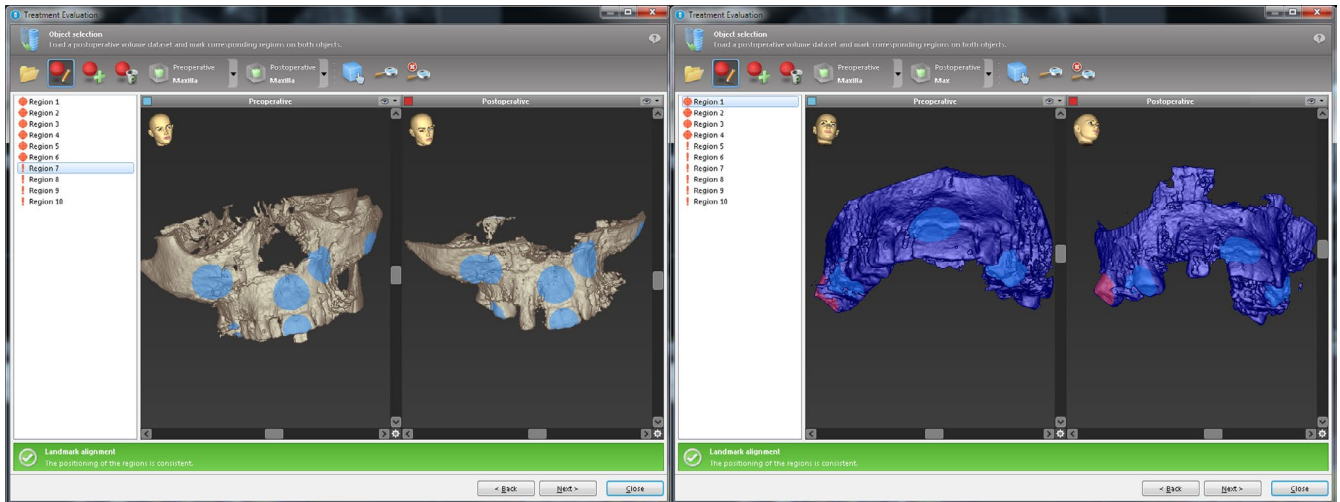
A “Standard Tessellation Language” (.stl) file was exported from the scan file. The file contained the surface geometry of the dentition as well as the scan bodies. The file was subsequently imported into the coDiagnostiX treatment evaluation module. The volume-rendered 3D model generated from the preoperative CBCT segmented with a threshold of 1,200 Hounsfield units (H) was aligned with the postoperative surface scan. No manual alignment was performed. The software detected the scan bodies in the postoperative IO scan automatically and generated metric values for the deviations between the planned and achieved implant positions.

### 2.6.2 | Postoperative CBCT

The postoperative CBCTs were taken 12–15 weeks after surgery. The settings were identical to the preoperative tomographs. The resulting volume dataset was imported into the coDiagnostix treatment evaluation module as DICOM files and segmented with a threshold of

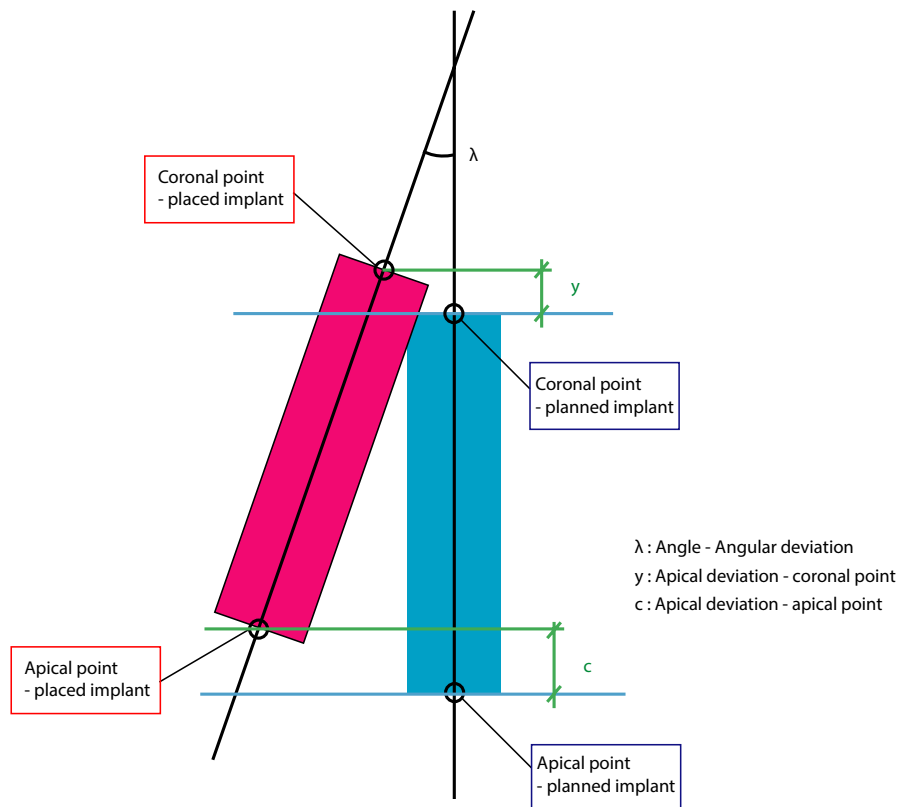


**FIGURE 4** Angular and depth deviations between the planned and achieved implant positions



**FIGURE 5** The deviations between the planned and achieved implant positions in the horizontal plane are described in tooth-oriented nomenclature: Vestibular and distal deviations

**FIGURE 6** The achieved implant position was calculated based on the scan bodies known dimensions

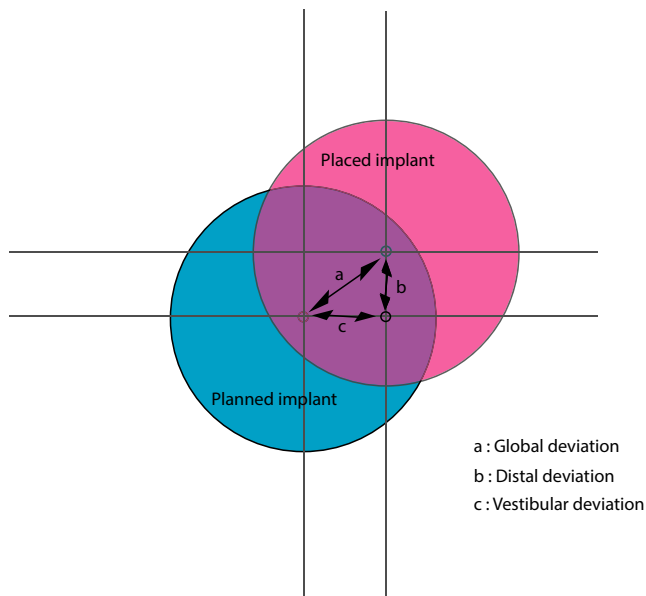


500H. The postoperative CBCTs containing visible representations of the implants were aligned with the preoperative CBCTs containing the planned implants using anatomical landmarks. The software calculated the metric deviations based on this alignment (Figure 7).

**2.7 | Statistical analysis**

Descriptive statistics were used to evaluate the differences between the planned and achieved implant positions as well as the difference between the postoperative CBCT and IO scan modalities.

The analysis of the data was performed by descriptive statistical analysis; mean ± standard deviation (SD) and ranges are shown. A 95% confidence interval is reported for each parameter. The normality of the difference between the two samples was tested graphically on a histogram and using the Shapiro–Wilk test. Paired sample *t* test was used to determine whether the mean difference between the two sets of observations is zero, when the normality assumption was satisfied; otherwise, the Wilcoxon test was used. Statistical analyses were performed using the Statistical Package - SPSS 17.0 (SPSS Statistics); the level of significance was set to *p* < 0.05.



**FIGURE 7** The volume-rendered model from the postoperative CBCT was aligned with the preoperative counterpart to calculate the achieved implant position

### 3 | RESULTS

Thirteen subjects, one male and twelve females, with a mean age of 48 years (range 37–78) were included in the study. A total of thirteen tooth-supported guides were made: ten intercalated and three free-end guides.

Seven molars, eighteen premolars, and three incisors were replaced by implant-retained prostheses. Fifteen implants were installed in the upper jaw and thirteen in the lower jaw. Eighteen implants were restored with single crowns, and ten were included in multi-unit restorations. Twenty-six implants were placed after raising a full-thickness flap, and two implants were placed using a flapless strategy.

Two implants were lost in one patient, due to infection, immediately after the surgery. One implant was further lost in another patient during the follow-up period. The survival rate after 2 years was 89.3%.

#### 3.1 | Measurements based on postoperative CBCT

The metric deviations at the coronal and apical points based on postoperative CBCT are presented in Table 1.

Mean angular deviation on free-end guides was 3.70 degrees and on intercalated guides was 2.16 degrees.

#### 3.2 | Measurements based on postoperative IO scanning

The metric deviations at the coronal and apical points based on postoperative IO scanning are presented in Table 1.

#### 3.3 | The difference between postoperative CBCT and IO scanning

The metric differences between CBCT and IO scanning at the coronal and apical points based are presented in Table 2.

Paired samples *t* tests comparing deviations measured with CBCT and IO scanning did not result in significant differences except for the apical deviations at the coronal and apical points.

The number of study participants was determined by the number of patients referred to the University of Oslo in the given time period with the need for treatment and with a medical status according to the inclusion criteria. A power calculation was not performed. Significant differences were not observed for angle, 3D offset, distal, and vestibular points for coronal and apical measurements. There is a possibility that a larger sample size may have detected significant differences between CBCT and IO scan on several of the measured parameters.

### 4 | DISCUSSION

This study evaluated the accuracy of implant placement that can be obtained with a system for guided implant surgery by measuring the deviations between the planned and achieved implant positions. The evaluation was performed with two different methods; the use of CBCT and intraoral (IO) scanning. Our results support other clinical studies where the deviation between the planned and

**TABLE 1** The metric deviations at the coronal and apical points based on postoperative IO scanning

	Angle	Coronal point				Apical point			
		3D offset	Distal	Vestibular	Apical	3D offset	Distal	Vestibular	Apical
CBCT Mean	2.58	0.9	0.29	0.55	0.5	1.11	0.45	0.74	0.49
CBCT SD	±2.07	±0.44	±0.25	±0.42	±0.38	±0.44	±0.39	±0.39	±0.38
CBCT Range	(0.7–10.6)	(0.03–1.91)	(0–1.03)	(0.3–1.66)	(0–1.79)	(0.44–2.1)	(0.4–1.45)	(0.12–1.44)	(0.1–1.78)
IO Scan Mean	2.59	0.87	0.3	0.58	0.41	1.07	0.39	0.77	0.4
IO Scan SD	±2.13	±0.39	±0.23	±0.41	±0.33	±0.43	±0.36	±0.45	±0.42
IO Scan Range	(0.6–10.9)	(0.13–1.77)	(0.01–1.01)	(0.4–1.61)	(0.5–1.23)	(0.47–2.12)	(0.1–1.41)	(0.1–1.61)	(0.06–1.22)

**TABLE 2** The metric differences at the coronal and apical points based on postoperative CBCT and IO scanning

	Coronal point CBCT—IO Scan				Apical point CBCT—IO Scan				
	Angle	3D offset	Distal	Vestibular	Apical	3D offset	Distal	Vestibular	Apical
Diff	-0.011	0.03	0.01	0.033	0.09	0.04	0.06	0.032	0.09
p	0.92	0.33	0.8	0.29	0.01	0.38	0.13	0.49	0.01
SD	±0.6	±0.17	±0.16	±0.16	±0.16	±0.22	±0.19	±0.23	±0.16
Range	1.60-0.0	0.0-0.56	0.0-0.35	0.03-0.32	0.01-0.56	0.01-0.60	0.01-0.47	0.01-0.61	0.01-0.56
95% CI	(-0.26 to 0.23)	(-0.03 to 0.1)	(-0.06 to 0.08)	(-0.1 to 0.03)	0.03 to 0.16	(-0.05 to 0.13)	(-0.02 to 0.13)	(-0.13 to 0.06)	0.03 to 0.16

achieved implant positions is within 1 mm and an angular deviation of 5 degrees (Besimo, Lambrecht, & Guindy, 2000; Ersoy et al., 2008; Sarment, Sukovic, & Clinthorne, 2003; Van Assche et al., 2007).

The present study reports data on the apical deviations on the installed implants. The mean deviation on the apical point was 0.49 ( $\pm$  0.38) mm (range 0.1-1.78). The apical deviation is perhaps most important as it reflects the position of the apex of the implant penetrating the bone. Inaccuracies in the installation procedure may result in damage to vital anatomy by the implant. Digital planning procedures take into account inaccuracies and identify a minimum distance between the implant and vital anatomy as a safety measure. In a recent study, Bover-Ramos and coworkers recommended to keep a safe distance equal to the highest value of the confidence interval (CI) (Bover-Ramos, Vina-Almunia, Cervera-Ballester, Penarrocha-Diago, & Garcia-Mira, 2018). Bover-Ramos recommended a safety distance of 1 mm. This number was supported by Soares and coworkers (Soares et al., 2012). The EAO consensus of 2012 recommends on the contrary only 0.5 mm safety distance in the vertical direction (Sicilia, Botticelli, & Working, 2012). The present study reports data which are within these recommendations and should therefore be regarded as clinically acceptable.

There has been substantial scientific effort during the last years to develop methods that will enhance the accuracy of static guided implant surgery (Ruppin et al., 2008; Schneider, Marquardt, Zwahlen, & Jung, 2009; Vasak et al., 2011; Wittwer, Adeyemo, Schicho, Birkfellner, & Enislidis, 2007). The deviations measured in guided implant surgery are the cumulative result of all errors in the planning, production, and placement of the dental implants (Jung et al., 2009; Kuhl et al., 2013; Schneider et al., 2009; Widmann & Bale, 2006). More clinical studies are needed in order to verify whether it is possible to further increase the accuracy of guided implant surgery. Cassetta and coworkers described intrinsic errors associated with guided implant surgery that may prevent an increase in accuracy (Cassetta et al., 2013). While the mean deviations between the planned and achieved implant positions are relatively low, the range of deviations is high. This may be due to the intrinsic errors described by Cassetta et al. as well as other contributing factors such as the effect of manual handling of the involved components in planning and execution of the procedure.

Guides in the present study were manufactured in a dental laboratory. The planning and production of the guides involved several technique-sensitive manual operations where human error could have had a significant influence. The most important factor was probably the intraoral positioning of the radiographic template during tomography as has been reported in the literature (Di Giacomo et al., 2005; Fortin, Bosson, Coudert, & Isidori, 2003). Any inaccuracies in the seating of the template during tomography would largely affect the end result as the template holds the reference elements which in turn translate the virtual planning into reality. The reference elements are used to match the radiographic template to the CBCT data (Kernen et al., 2016). Another contributing source of inaccuracy is the procedure of drilling holes in the template, which is made with a system-specific laboratory device. The transformation of the radiographic template into a surgical guide is a highly

technique-sensitive and time-consuming manual process where the handling of the laboratory device (drilling machine) probably is the most important factor. Laboratory-manufactured guides have as well some clinical advantages. The possibility to verify the tooth architecture in a patient's mouth is a significant advantage and particularly important when anterior restorations are planned. An esthetic evaluation in which the extra-oral situation needs to be taken into account is to date not possible with a digital process.

Different guided implant drilling systems are available. A system with separate keys was used in our study. The keys allowed burs with varying diameters to be fitted in the sleeve incorporated in the surgical guide. The adaptation of the burs in the drilling guide is a significant procedural factor documented by Lee et al. (Lee, An, Hong, Jeon, & Lee, 2016). Exact adaptation between the metal sleeves incorporated in the guide, keys, and burs is important for the accuracy (Schneider, Schober, Grohmann, Hammerle, & Jung, 2015), but surgeons' manual handling of the bur through the guide is probably equally important. Van Assche and coworkers documented that significant deviations may result from improper handling of the surgical instruments (Van Assche & Quirynen, 2010). The guided surgery procedure should thus be simplified as much as possible to further increase the accuracy.

The calculation of differences between the planned and achieved implant positions after guided implant surgery is most often based on postoperative computed tomography. This methodology to evaluate the achieved implant positions after guided implant surgery is an invasive procedure and exposes the patient to additional radiation. Different alternatives to postoperative tomographs have thus been proposed to minimize the exposure to radiation. Nickenig and coworkers proposed to perform postoperative tomography on plaster casts with embedded implants (Nickenig & Eitner, 2010). Our study aimed to verify another method to calculate the difference between the planned and achieved implant positions with the use of IO scanning of the implants.

The quality, precision, and handling of IO scanning devices have improved considerably over the last two decades. A digital image of an abutment tooth or implant may be recorded with acceptable accuracy with a noninvasive light-emitting device. The surfaces are described in a 3D environment, and the digital impressions may be used to manufacture prosthetic restorations or as digital study casts. The *in vivo* accuracy of full-arch digital study casts has been verified in several studies (Flugge, Schlager, Nelson, Nahles, & Metzger, 2013; Naidu & Freer, 2013; Wiranto, Engelbrecht, Tutein Nolthenius, van der Meer, & Ren, 2013). The procedure of using digital implant impressions to produce single implant restorations has been reported (Moreira, Rodrigues, Pinho, Fonseca, & Vilaca, 2015), and several authors have further confirmed that the IO scanners are able to digitize the intraoral surfaces with acceptable accuracy (Ender & Mehl, 2011; Guth, Keul, Stimmelmayer, Beuer, & Edelhoff, 2013).

The calculation of the postoperative implant positions in the present study was performed based on the fusion of the preoperative CBCT and postoperative IO scan (Rangel, Maal, Berge, & Kuijpers-Jagtman, 2012; Rangel et al., 2013; Widmann et al., 2015)

compared with fusion of preoperative and postoperative CBCT. IO scanning of dental implants requires that scan bodies are attached to the implants. These will protrude from the mucosa and make the subsequent scanning procedure straightforward. The scanning results require that the scan body is correctly installed on the implant. Stimmelmayer and co-workers (Stimmelmayer, Erdelt, Guth, Happe, & Beuer, 2012) reported a difference between placing scan bodies on laboratory implant analogs and original implants. Factors like inter-implant distance and implant angulation may affect the results as well as the operator's clinical experience with IO scanners (Gimenez, Ozcan, Martinez-Rus, & Pradies, 2014). Results from the postoperative evaluation based on computer tomographs and IO scanning revealed no significant differences except for the apical deviations at the coronal and apical points.

A 95% confidence interval is reported for the differences between CBCT and IO scan measurements. It is not possible, from a statistical standpoint, to exclude that a relevant difference may exist due to the limited number of samples included in this study.

More recent technologies have been introduced in which IO scanning is combined with computed tomography and digital design software. The number of manual working steps is reduced with a potential for increased accuracy (Kuhl, Payer, Zitzmann, Lambrecht, & Filippi, 2015).

The survival rate of the implants included in this study was 89.3% after 2 years.

Two implants were lost in the same patient due to infection immediately after surgery. The surgical report stated no significant problems during the procedure.

One implant was lost in another patient during the healing period. The surgical report stated the presence of hard cortical bone making the osteotomy difficult. It is known that implant loss may be caused by a temperature rise resulting from an inferior cooling of the bur during the drilling process (Carvalho et al., 2011; dos Santos et al., 2014). Clinicians need to be aware of problems associated with inferior cooling of the burs when using guided implant surgery.

## 5 | CONCLUSION

Guided implant surgery with a static approach using surgical guides made by dental technicians may yield clinically acceptable deviations between the planned and achieved implant positions. The accuracy of the implant installation observed in this study was within the angular and apical/coronal deviations reported by other investigators.

The findings in the present study indicate that IO scanning technologies may replace CBCT as a method to evaluate the differences between the planned and achieved implant positions in clinical *in vivo* studies on guided implant surgery.

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## CONFLICT OF INTEREST

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## SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.













## Errata list

Candidate: Henrik Skjerven

Title thesis: 1 Influence of digital design and fabrication of surgical guides on the accuracy of implant placement - A doctoral thesis

Page	Line	Footer	Original text	Errata type	Cor text
150	51		...(No.2011/869)	Cor	...(No.2014/1750)
128	18		...(SD 1.90; range 0.00– 6.04).	Cor	...(SD 1.90; range 0.00–19.04).