CHAPTER 1

General Introduction
When looking at computed tomography, implant planning software and guided implant surgery it can be concluded that the digital era has merged into implant dentistry. Computer-aided design (CAD) technique is being integrated into patient treatment planning, and computer-assisted manufacturing (CAM) is becoming more and more popular. Different concepts and technologies have been widely introduced into the scientific literature in an attempt to achieve perfect safety and precision of implant treatments. The ITI consensus paper on guided surgery\(^1\) distinguished two general concepts in image-guided surgery:

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

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

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

• **Surgical template (surgical guide)**: Laboratory-fabricated guide based on ideal prosthetic positioning of implants used during surgery.

• **Stereolithographic guide**: Surgical guides that assist placement of implants *in vivo* in the same location and direction as those in a planned simulation. Stereolithography (3D layering and 3D printing) is a technique that is used to create solid plastic 3D objects from CAD drawings by selectively solidifying an ultraviolet-sensitive liquid resin (photopolymer) using a laser beam.

• **Immediate loading**: Application of a functional or non-functional load to an implant at the time of or shortly after surgical placement, generally loaded within 48 h of implant placement.

• **CAD/CAM**: Acronym for computer-aided design/computer-assisted manufacturing.

All existing approaches in guided surgery follow a similar (semi) digital workflow: The digital CT (also including cone beam CT [CBCT]) images of patients wearing a prosthetic setup can be converted into a virtual 3D model of the treatment area using planning software. This provides the practitioner with a realistic view of the patient’s bony anatomy, thus permitting virtual execution of the surgery in an ideal, prosthetically driven manner. For this reason, and to create some references to transfer the prosthetic information to the CT images, the so-called double-scanning technique was introduced. The denture or the prosthesis replica is prepared before scanning. At least 5 small (Ø 1 mm) gutta-percha balls were inserted in the prosthetic surface to act as radiopaque markers that are randomly spread over the prosthesis. The CT protocol consists of 2 scans. First, the patient, wearing the index and the prosthesis, was scanned with the occlusal plane parallel to the axial slices. Immediately after the scanning, a second CT scan of the prosthesis itself was performed using the same CT scanner settings. The two resulting sets of axial CT slices were fused on the basis of the radiopaque gutta-percha markers. This double-scan procedure attempted to accurately image the
prosthesis and facilitate easy fusing of the prosthesis CT scan to the patient CT scan. Different approaches have been introduced to transfer this planned digital information to the clinical situation. Mechanical positioning devices or drilling machines convert the radiographic template to a surgical template by executing a computer transformation algorithm, using a plaster cast (analogue, not digital) of the treated jaw. In other approaches, stereolithography or rapid prototyping is used to fabricate a surgical guide. These computer-designed surgical guides in combination with CAD software and CAM technology were also used to create a superstructure prior to the actual implant surgery. To make this possible, a plaster model that included the planned implants was prepared using the surgical guide. An optical scan device (e.g. Procera, Nobel Biocare Sweden) digitalised this information again to allow CAD software design and CAM of the superstructure. These surgical guides that were produced using these techniques were then positioned on the mucosa, bony structure, or dentition depending on their design to guide the osteotomy and implant placement in the pre-planned positions. In the case of procedures in which a superstructure was fabricated, the patients were also prosthetically restored either immediately or shortly after surgery. These surgical guidance approaches have been subject to different clinical and in vitro studies. On the basis of 2 clinically advanced cases, Sarment et al. introduced in vitro the use of stereolithography to produce a radiographic template that not only allows the precise translation of the treatment plan directly to the surgical field but also offers many significant benefits over traditional procedures, such as surgical guidance for implant insertion, flapless and non-invasive implant surgery, and a decreased risk of damaging vital anatomic structures like the mental nerve and the maxillary sinus. In a clinical study conducted in 2005, 6 stereolithographic surgical guides were used in 4 patients and a total of 21 implants were placed. After surgery, a new CT scan was taken and the software was used to fuse the planned and placed implant images for comparison of the locations and axes. On average, the following distance differences were measured between the planned and placed positions: 1.45 ± 1.42 (SE) mm at the implant shoulder and 2.99 ± 1.77 mm at the implant apex. In all patients, a greater distance between the planned and placed positions was measured at the implant apex than at the implant neck. As a result, we concluded that, in addition to the suggestion that computer-aided rapid prototyping of surgical guides may be useful in implant placement, stereolithographic fabricated surgical guides require improvement to provide better stability of the guide during the surgery,
especially in cases of unilateral bone-, mucosa-, and non-tooth-supported guides. As mentioned before, considering the idea that the use of pre-operative planning and guided surgery could reliably predetermine the position of dental implants, some companies introduced pre-fabrication of prosthetic devices followed by immediate loading of dental implants at the time of surgical placement using CAD/CAM technology.

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

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

Komiyama et al. evaluated the outcome of immediately loaded implants installed in edentulous jaws following computer-assisted virtual treatment planning combined with flapless surgery. Twenty-nine edentulous patients were treated using the Nobel Guide protocol for surgical planning, fixture installation, and immediate loading of a pre-fabricated

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

(2) Errors that occurred during surgery

Thus, the first idea was to establish stable references by inserting specially developed mini-implants before the treatment was enhanced. These mini-implants would remain during the complete procedure as fixed reference points. In this way, the prosthetic guide could be inserted in a reliable and reproducible manner during the CT imaging as a future surgical template when screwed onto the mini-implants. Since all systems described in the literature were CT-based, the primary error probably occurred right at the beginning of the workflow. Compared the accuracy of CBCT and multi-slice CT (MSCT) for linear jaw bone measurements. An *ex vivo* formalin-fixed human maxilla was imaged with both CBCT and MSCT. The MSCT images were reconstructed using different reconstruction filters to optimise bone visualisation. Before scanning, triplets of small gutta-percha markers were glued onto the soft tissues overlying the top of the maxillary bone and on both sides of the alveolar ridge to define a set of reproducible linear measurements in 11 planes. Image measurements were performed by 2 observers. The gold standard was determined by 3 observers who took physical measurements with a caliper. They concluded that both CBCT and MSCT yield sub-millimeter accuracy for linear measurements on an *ex vivo* specimen. Hassan et al. investigated the influence of patient scanning position in an *in vitro* study. The influence of the position of the patient’s head in the scanner on linear measurement accuracy was assessed on 3D surface-rendered images generated from CBCT by comparing 2D slices and 2D lateral and postero-anterior cephalometric projections. Eight dry human skulls were scanned twice using a CBCT in an ideal and a rotated position and the resulting datasets were used to create 3D surface-rendered images, 2D CT slices, and 2D lateral and panoramic projections. Ten linear distances were defined for cephalometric measurements. The physical and radiographic measurements were repeated twice by 3 independent observers and were compared using repeated measures analysis of variance. Radiographic measurements were also compared between the ideal and the rotated scan positions. The radiographic measurements of the 3D images were closer to the physical measurements than the 2D slices and projection images. No statistically significant differences were found between the ideal and the rotated scan measurements for the 3D images and the 2D CT slices. A statistically significant difference (P < 0.001) was observed between the ideal and rotated scan positions for the 2D projection images. The findings indicate that measurements based on 3D CBCT surface images are accurate and that small variations in the patient's head position do not influence measurement accuracy. However, as measuring of a certain distance or a line seems to be quite accurate on CT or CBCT images even when the patient positioning in the scan...
devices is not optimal, the so-called artefacts caused by metals like mini-implants used in our
study can result in measurement inaccuracy. For this reason, the fiducial markers (what we
called the screw complex) were designed to not only to screw the CT template on the mini-
implants but also to contribute to the determination of the position of the mini-implants. Birkfellner et al.\textsuperscript{31} reported the use of fiducial markers in image-guided implant dentistry. In
addition to the accuracy of the tracking system based on fiducial markers, the precision of
localising a specific position on 3D pre-operative imagery is governed by the registration
algorithm that conveys the coordinate system of the pre-operative CT scan to the actual
patient position. Two different point-to-point registration algorithms were compared for their
suitability for this application. The accuracy was determined separately for the localisation
error of the position measurement hardware and the error as reported by the registration
algorithm. The investigators found that a registration algorithm based on the use of 3 fiducial
markers is the superior approach for point-to-point matching in terms of mathematical
stability. In a more recent study, Widdmann et al.\textsuperscript{32} investigated \textit{in vitro} registration and
targeting accuracy for surgical navigation in the edentulous jaw based on 3 fixed intra-oral
reference points. For evaluation of the registration accuracy, the fiducial registration error
was recorded and application accuracy was evaluated by the fusion of postsurgical CT scans
of the drilled dental stone casts with the pre-surgical planning computed tomogram. They
concluded that 3 fixed intraoral reference points successfully support a registration
mouthpiece and provide \textit{in vitro} registration and targeting accuracy that is comparable to
tooth-supported registration templates or bone marker registration. Another cause of
inaccuracy might be the multiple data transfers that occur between the patient and the
computer during the procedure. The scanned image data (DICOM) needs to be imported into
the CAD/CAM environment in order to fabricate the surgical guide following
stereolithographical principles. Some procedures (e.g. Nobel Guide) use a fabricated
computed drill guide to drill the future implants in a cast made after taking an impression of
the jaw to be treated. This cast is subjected to an optical scanning procedure (e.g. Procera) to
fabricate a CAD/CAM superstructure. These multiple data transfers could accumulate minor
errors that might result in inaccuracy. The surgical procedure and the osteotomy protocol can
also influence the final correct 3D position of the inserted implant, which might differ from
the planned position. The drill precision and the correct pre-planned 3D position of the
implants were considered crucial to achieve accuracy in our study. For this reason, a new drill
design and drilling sequence was introduced in our study, as was a tool to physically control
the depth during implant insertion. This tool was evaluated in both \textit{in vitro} and in a clinical
trial. It is the purpose of this thesis to address various issues related to computer-guided
surgery, CAD/CAM technology, and immediate loading. The following questions were addressed in this thesis: How precise is the digital approach in guided surgery and immediate loading? How reliable is this technique in clinical situations? How can the precision of superstructures be analysed? How reliable and reproducible are these measuring techniques? Is it possible to use this protocol for all clinical situations?
References


