Guided surgery and immediate loading

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Summary And Future Perspectives

Despite the rising popularity of guided surgery and immediate loading, profound scientific evidence is lacking to support this approach in dental implant treatment.
Nevertheless, the possible advantages of guided surgery protocols such as flapless and minimally invasive surgery, protection of vital anatomical structures, and immediate restoration have been extensively highlighted as marketing tools in the dental implant industry. The introduction of **Cone Beam CT** (CBCT) scanning and the increasing availability of this technique to dental offices have made the digitalisation of implant dentistry more and more accessible.
Different companies have developed software packages and technologies to deliver a digital approach to treating patients using dental implants. These software packages for guided surgery are similar and are based on comparable technology. However, the manners in which the drill guides are fabricated differ.
Stereolithography, rapid prototyping, and a model-based approach using computer algorithms are among the most commonly applied technologies.
On the other hand, our systematic review showed that, despite the different levels of research quality for computer-assisted implant placement, an evaluation of the evidence suggesting that computer-assisted surgery is superior to conventional procedures in terms of safety, implant precision, morbidity, and efficiency has yet to be performed.
Some studies have demonstrated that the maximum observed deviations from computer-aided planned implant positions exceeded what one might call clinically acceptable levels. Thus, future long-term clinical data are necessary to evaluate its clinical success and to justify the additional CBCT-associated radiation doses, effort, and costs associated with computer-assisted implant surgery **(Chapter 1)**.
Why are there large deviations from the planned implant position? What are the possible causes of the deviations and how can we improve this technique's precision?
Various hypotheses have been put into consideration to address this question:

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

In an *in vitro* study (Chapter 3), we demonstrated that insertion of mini-implants as references prior to the actual implant insertion could create a permanent reference base throughout the entire treatment procedure.
Calibration flags, what we refer to as screw complexes, that act as fiducial markers were also developed to assist clinicians with identifying the reference mini-implants on the CT images.
An improved drilling sequence with a specifically developed drill design and an instrument to physically control the implant depth were introduced in an attempt to improve guided implant surgery precision **(Chapter 2)**.
To analyse the procedure precision, 2 different approaches were followed:

- Optical scan analysis
- Strain gauge analysis

Both an acrylic resin and plaster models were prepared to mimic the edentulous mandible. After 3 mini-implants were inserted in the acrylic resin model, a CBCT scan was performed. Data comprising 6 implants were imported into the planning software. A drill guide and a titanium framework were designed in the same virtual environment and then milled using a fully digital computer-aided design/computer-assisted machining protocol, providing a completely digital approach. Six implants were inserted into the acrylic test model using the drill guide screwed onto the mini-implants. After an impression was made of the acrylic resin model with the 6 implants, a second model (plaster model) was prepared. A second milled titanium structure was fabricated following optical scanning of the acrylic resin model (traditional optical scanning approach). Strain gauge measurements were done on both structures when attached to both models. To validate the results, a high-accuracy industrial optical scanning system was used to capture the connection geometry, and the measurements were compared.
The accuracy and standard deviations (SD) of the superstructures made after the complete digital approach were 19.2 (17.9), 21.5 (28.3), and 10.3 (10.1) μm for the x-, y-, and z-axes, respectively.
The accuracy (SD) of the impression-based superstructure using strain gauges and measured misfits was 11.8 (10.5), 19.7 (11.7), and 16.7 (8.2) μm for the x-, y-, and z-axes, respectively. We concluded that the misfit of the digitally designed and produced superstructure on the digitally planned and inserted implants compared to the analogue impression technique was clinically insignificant **(Chapter 2)**.

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

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

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

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

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

A total of 240 final superstructures were inserted and immediately loaded; 229 (95.4%), 146 (93.6%) in the maxillary jaw and 83 (98.8%) in the mandibular jaw, survived. Ten of the 11 implants lost in the upper jaw occurred in patients with an augmented sinus. All of the final restorations fit sufficiently. Having evaluated implant and superstructure success, we concluded that reference-based guided surgery seems to be a reliable treatment option for the treatment of edentulous patients. The CAD/CAM superstructure, inserted and loaded immediately after guided implant insertion, was produced digitally with a precise fit and with the most acceptable occlusion and aesthetics **(Chapter 6)**.

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

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

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