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

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Abstract

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

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

Early treatment protocols with osseointegrated implants used an undisturbed healing period to allow bone to heal around the endosseous implant. The initial protocol gradually evolved to one in which implants could be placed and loaded immediately if the implants were rigidly splinted, thereby reducing implant movement to less than 100 µm.

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

Materials and Methods

This pilot study was divided into an in vitro phase and a clinical phase, which involved the treatment of two patients. The in vitro phase of the study, a cast of a partially edentulous arch with a unilateral posterior partially edentulous space in the right maxilla was used. A test cast (model A) was fabricated (Ludo Beckers) using methacrylate resin containing barium sulfate to provide radiodensity (Fig 1a). This cast was used to evaluate the precision of the cast using a strain gauge analysis. It represented a partially edentulous arch with teeth present in the maxillary canine and left premolar regions. Simultaneously, two patients were treated with the same treatment protocol (Figs 1b through 1f). Both patients signed an informed consent document.
A mini-implant (Straumann) was inserted in the maxillary right tuberosity region to serve as the first reference point in test model A. Two custom-made brackets connected to a prosthetic table similar to that of the mini-implant were attached to the two canines in test model A (Figs 2a and 2b). Both patients underwent similar procedures in which impressions of the arches were made with polyether impression material (Impregum, ESPE). Alginate impressions were made of the opposing arches and soft tissue casts were fabricated. After the bite registration procedure, a wax-up of the intended prosthetic rehabilitation was produced. After approval of the wax-up, CT setups were delivered using an acrylic resin containing barium sulfate (Vivotac/orthotak, Ivoclar Vivadent). These diagnostic CT setups represented the anticipated definitive prosthesis. Three reference brackets per arch were attached to the casts of both patients using dental wax. Because these patients presented with tooth-bound edentulous spaces, no mini-implants were used, but reference brackets were used as reference points to ensure the stability of the surgical guide. Three screw complexes (used for the CT scan calibration) were connected to the screw connection of the brackets. An acrylic resin key was then fabricated on the cast and connected carefully to the brackets and the barium sulfate (prosthetic wax-up) teeth (Figs 2c through 2e). A cone beam CT scan (Veraviewepox, Morita) was used to scan the test model and the patients, with the specially designed screw complex attached to the mini-implants and the brackets. The screw complex determined the position of the mini-implants on the CT images.13-14 The screw complex consisted of a cylinder with a defined length and a radiopaque gutta-percha marker point placed on the top. The radiopaque gutta-percha points were 1-mm-diameter spheres and could be visualized on the CT scan images without artifacts.

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

In both patients, two implants with different thread designs (Straumann and MIS) were virtually inserted with consideration of the available bone, the planned definitive restoration, and the underlying anatomical structures. The difference in implant thread geometry can be helpful to achieve primary stability in different types of bone. These kinds of implants can be swapped during the operation depending on the bone quality without affecting the outcome of the prefabricated framework, since they have identical prosthetic systems. The planning data were exported into a computer-aided design (CAD) software program, where the surgical template and the framework of the future superstructure were designed (Fig 4) using the same data set as the planning software. The design data were imported into the planning software, where the fit was virtually checked.
After the planning and design were approved, the data were sent to a milling company (ES Tooling). A simultaneous five-axis milling device fabricated the surgical templates in pink composite and the titanium frameworks for test model A and the two patients (Fig 5). For both patients, titanium frameworks were sent to the dental laboratory (Corpix, Kasterlee, Belgium) to be finalized with veneered porcelain (Fig 6).

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

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

Preparation of the implant sockets was performed using a sequence of drills. The drilling sequence involves three groups of different drill diameters: 2.2, 2.8, and 3.5 mm (Fig 8a). The first drill sequence (2.2 mm) starts with a flat-headed drill, which flattens the entry point. The following drills increase by 2 mm in length per step, up to the last drill (7 mm in length).

In this way, heat and undesired tilting are prevented during the osteotomy. The second drill sequence (2.8 mm) is similar to the first one; it begins with a flat drill and ends with the last drill, which is 10 mm long. The final drill sequence (3.5 mm) determines the length of the inserted implants, starting with 10 mm and ending with 12 mm (Fig 8a). The guiding segment of all the drills has the same diameter, which fits in the surgical guide in a precise manner.

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

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

Probing depths and Bleeding Index were recorded 6 months after surgery. The fit of the superstructure on test model A was measured by a three-dimensional tension measurement.
method using strain gauges. The length of each cylinder (connection posts from the superstructure to the implants) was 12 mm to allow for placement of the strain gauges. Four strain gauges were attached along the long axis of each cylinder of the superstructure at 90-degree angulations from each other (Fig 14). The axes of the different cylinders were oriented in the same direction, so that it was possible to calculate the total measured misfit. This misfit-induced tension is measured for all axes by an electrical circuit called a Wheatstone bridge. This is used to measure an unknown electrical resistance by balancing two legs of a bridge circuit, one leg of which includes the unknown component. In the test model, the changes in resistance in the strain gauges are a result of force induced stretch or shrinkage (plus or minus). The misfit and tension in all three axes were measured using the four strain gauges connected by Wheatstone bridges.

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

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

**Figure 1a:** Test model A: partially edentulous cast of the maxilla
**Figures 1b and 1c:** Patient with partial edentulous maxilla

**Figures 1d to 1f:** Patient with partially edentulous maxilla and mandible
**Figures 2a and 2b:** Reference elements: one mini-implant and two brackets were attached to test model A. Calibration flags, as part of the screw complex, fixing the scan denture with dentition (made out of barium resin) to the mini implants or reference brackets. Gutta percha markers are situated on the plastic flags indicating the position of the mini implants and reference brackets on the CT images.

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

**Figure 3:** Planning and CAD/CAM phase. The CT images were imported into the planning software and the implants were virtually inserted.
Figure 4: The data were exported from the planning software and imported into the CAD software, where the framework and the surgical guide are designed.

Figure 5: The frameworks and the surgical guide are milled. Two implant replicas are inserted into the master cast using the surgical guide. The framework is further processed and finished.
Figure 6: The screw-retained finished porcelain-fused-to-metal restorations are ready before implant insertion. The superstructure is connected directly to the implants without the use of any abutments.
Figure 7a: Brackets are connected to the reference teeth in the same position as on the diagnostic cast using the transfer key.

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

Figure 8a: The drilling sequence. Each drill has an identical guiding segment, whereas the cutting segments differ in length and diameter.
Figures 8b and 8c: The osteotomies are guided using drills with stops to achieve the planned positions.

Figure 9: The guided osteotomy and guided implant insertion. The precision pin helps ensure the correct (predetermined) vertical position of the implants.
Figure 10a: The implants have been inserted through the surgical guide on the test model, and the guide has been removed.

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

Figure 11: Superstructures in place on the implant level (no abutments) immediately after implant insertion.
Figure 12: Postoperative radiographs of patients
Figure 13: One-year postoperative radiographs

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

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

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

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

Table 1: Results of In Vitro Measurements

<table>
<thead>
<tr>
<th>Implants</th>
<th>x-axis (µm)</th>
<th>y-axis (µm)</th>
<th>z-axis (µm)</th>
<th>RMS (µm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implant 1</td>
<td>24.4 ± 3.6</td>
<td>16.4 ± 2.4</td>
<td>8.7 ± 1.8</td>
<td>30.6</td>
</tr>
<tr>
<td>Implant 2</td>
<td>29.7 ± 3.7</td>
<td>60.5 ± 6.7</td>
<td>10.8 ± 1.9</td>
<td>68.3</td>
</tr>
<tr>
<td>Implant 3</td>
<td>45.9 ± 6.9</td>
<td>4.5 ± 1.9</td>
<td>6.2 ± 0.8</td>
<td>46.6</td>
</tr>
<tr>
<td>Implant 4</td>
<td>6.8 ± 1.7</td>
<td>17.9 ± 1.6</td>
<td>16 ± 2.6</td>
<td>24.6</td>
</tr>
<tr>
<td>Total average</td>
<td>26.6</td>
<td>24.8</td>
<td>10.4</td>
<td>42.6</td>
</tr>
</tbody>
</table>

Table 2: Implant and Clinical Data for Treated Patients

<table>
<thead>
<tr>
<th>Implant data</th>
<th>Left</th>
<th>Right</th>
<th>2nd M</th>
<th>1st M</th>
<th>2nd PM</th>
<th>1st PM</th>
<th>Canine</th>
<th>1st PM</th>
<th>2nd PM</th>
<th>1st M</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient 1 (max)</td>
<td>MIS, 4.1 × 8 mm</td>
<td>MIS, 4.1 × 8 mm</td>
<td>MIS, 4.1 × 11.5 mm</td>
<td>MIS, 4.1 × 11.5 mm</td>
<td>MIS, 4.1 × 11.5 mm</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient 2 (max)</td>
<td>TE 4.1 × 12 mm</td>
<td>TE 4.1 × 12 mm</td>
<td>MIS, 4.1 × 10 mm</td>
<td>MIS, 4.1 × 10 mm</td>
<td>MIS, 4.1 × 10 mm</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient 2 (mand)</td>
<td>S 4.1 × 10 mm</td>
<td>TE 4.1 × 10 mm</td>
<td>MIS, 4.1 × 10 mm</td>
<td>MIS, 4.1 × 10 mm</td>
<td>MIS, 4.1 × 10 mm</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Probing depth (mm) (M, D, B, P)

Pt 1    | 2, 2, 3, 2 | 2, 2, 2 | 2, 3, 2, 2 | 2, 3, 3, 3 |
Pt 2 (max) | 2, 3, 2, 3 | 3, 3, 3, 3 | 2, 2, 2, 2 | 3, 2, 3, 2 |
Pt 2 (mand) | 2, 2, 2, 2 | 2, 3, 2, 2 | 2, 2, 2, 2 |

Bleeding Index

Pt 1 (max) | 0, 0, 0, 1 | 0, 0, 0, 0 | 0, 0, 0, 0 |
Pt 2 (max) | 0, 0, 0, 1 | 1, 0, 1, 1 | 0, 0, 0, 0 | 0, 0, 0, 0 | 0, 1, 0, 0 |
Pt 2 (mand) | 0, 0, 0, 0 | 0, 1, 0, 0 | 0, 0, 0, 0 | 2, 2, 2, 2 | 2, 2, 2, 2 | 2, 3, 2, 2 |

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

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

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

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

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

Conclusion

Within the limitations of this pilot study, which included an in vitro analysis and the treatment of two patients, it can be concluded that this reference-based digital procedure, in
which a superstructure is fabricated on the basis of calibrated computed tomographic images only, can result in a high level of precision. With the level of accuracy reached, a definitive fixed prosthesis could be fabricated in different clinical cases prior to implant placement. All implants survived, with pleasing esthetic and clinical outcomes.

**Acknowledgments**
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