In vitro accuracy evaluation of Implant 3D Computer Guided Implant System

Abstract:
The aim of this study was to evaluate in vitro the accuracy and precision of Implant 3D guided implant surgery system, using a digital processing image software.

Materials and Methods: Two acrylic resin model with artificial gum were prepared to represent edentulous mandibles. After insertion of three mini-implants used as precision pin in the acrylic resin model, a cone-bean computed tomography (CBCT) scan was performed with individual diagnostic template fitted on. Stereolithographic guide was created using computer-aided design/computer-assisted manufacturing technology and virtual planning software. Twelve implants (6 for every model) were inserted using the drill guide blocked to the mini-implants exactly at the depth that had been determined during the planning phase. After implant placement, the model mandible was subjected to another CBCT scan to compare the actual implant positions with the planned positions. The pre-and post-implantation CBCT images were superimposed using digital processing image software to evaluate the linear and angular deviations between the virtual planning data and the surgical results.

Results: The mean angular deviation between the virtual and actual positions of twelve placed implants was 2.44 degrees (SD 1.98). The mean shoulder radial deviation was 0.23 mm (SD 0.14), the mean implant center deviation was 0.21 mm (SD 0.17), and the mean apex radial deviation was 0.14 mm (SD 0.11). The mean apical point deviation was 0.15 mm (SD 0.29); while at the entry point the mean shoulder mesial and distal radial deviations were 0.3 mm (SD 0.12), and 0.27 mm (SD 0.19), respectively.
Conclusions: Within the limitations of the present study, the in vitro investigated Implant 3D Computer Guided Implant System showed promising accuracy in virtual implant placement.

Introduction:
One of the most important development in the field of implant dentistry is the introduction of computed tomography (CT) in conjunction with Computer-aided design/computer assisted manufacturing (CAD/CAM)-generated surgical guides. The visualization obtained from CT scans permits precise surgical planning for implant placement since anatomic limitations, bone morphology and the surgical site underneath the soft tissues can be evaluated precisely (Dula et al. 2001, Besimo et al. 2000). By using CT-assisted implant planning systems, it is possible to pre-surgically determine, with a high degree of accuracy and with 3D views, the best position and inclination for implant placement. To transfer the preoperatively planned implant position into the patient’s mouth, surgical templates based on the preoperative set-up and virtual implant planning, are either fabricated manually in a dental laboratory or stereolithographically by CAD/CAM technology. Systems which use this kind of procedure are called “template-based” or “static”. Other systems which use intra-operative optical tracking of the hand-piece position with cameras and guide the surgeon “real-time”, are called “dynamic” (Jung et al. 2009). Both static and dynamic systems have well-documented advantages and disadvantages, however, their application accuracy levels seem to be similar (Fortin et al. 2002; Ruppin et al. 2008). With the introduction of the cone-beam CT (CBCT) technology (Mozzo et al. 1998), which reduced radiation exposure (Ludlow & Ivanovic 2008), the operational availability of 3D diagnosis has extremely expanded in dental practices, and different static systems are now available for 3D guided implant treatment (Jung et al. 2009). Several clinical studies have demonstrated the value of 3D guided systems for diagnosis, planning, and placement of dental implants (van
Steenberghe et al. 2005; Sanna et al. 2007; Komiyama et al. 2008). However, different issues regarding this kind of technology are still open to debate, since it requires a complex consequential protocol, that involved several steps: 1) the fabrication of a radiographic template, 2) the CBCT acquisition with the template in position, 3) the computer assisted implant planning, and 4) the fabrication and use of a surgical guide for drilling and implant insertion. Every step of the sequence is prone to errors (Widmann & Bale 2006). Accordingly, it is important to determine the most precise system for accurately and securely transferring the CAD plan to the surgical environment. The accuracy of various computer-guided implant treatment systems, defined as “the deviation in location or angle of the plan compared to the result”, (Widmann & Bale 2006), has been well documented over the years (Jung et al. 2009; Schneider et al. 2009; Van Assche et al. 2012). Factors reported influencing the accuracy of the computer-guided approach in a negative way has been identified in bone-supported guides, in the use of multiple templates, and in the lack of guide fixation (Van Assche et al. 2012). To overcome some of limitations related to these factors, the Implant 3D system evaluated in the present study, provides the use of the three mini-implants as reference points of guide fixation, and the use of the same data for planning, designing the surgical guide, and surgery transformation of the same radiological template in surgical guide. Since the measuring the accuracy of implant placement vs. planning in vivo involves the acquisition of a post-surgical CBCT, which is medically unjustifiable in most clinical cases, and the use of human cadaver evolves ethical considerations, the present study was designed to assess the in vitro accuracy of the Implant 3D guided implant system, by evaluating the difference between planned and actual implant positions on pre- and post-operative CBCTs, using a resin jaw models and a digital processing image software.
Materials and Methods:

The study, designed to follow in vitro a clinical sequence of a computed guided implant treatment from planning to implant insertion, was conducted using acrylic resin mandibles covered with a silicone material to represent gingival tissue (Fig. 1). Three mini-implants (7.5 mm long, 2.5 mm in diameter) were inserted covered with a silicone material to represent gingival tissue in every model in the retromolar area bilaterally and in the mandibular midline to establish a tripodial distribution. Mini-implants remain during the complete procedure as fixed reference points. In this way, the prosthetic guide can be inserted in a reliable and reproducible manner during the CT imaging as a future surgical template when screwed onto the mini-implants. Tahmaseb et al. (2009, 2011) previously evaluated this technique, showing that the use of reproducible fiducial markers, consisting of mini-implants, allows placing the implants in the correct vertical dimension that was calculated during computerized planning.

After insertion of the mini-implants, impressions were taken using impression coping and a polyether impression material. Models were poured with gypsum (WhipMix Quickstone Laboratory Stone, Louisville, KY, USA), using the mini-implant analogues. The diagnostic CT setup was delivered using an acrylic resin containing barium sulfate (Vivotac, Ivoclar Vivadent, Schaan, Liechtenstein). The CT template, which represents the future restoration, was then screwed onto the mini-implants before the CBCT recording, using a dedicated screw compex (Fig. 2). Pre-operative CBCT scans of the models with the templates in place were acquired using Brillancet CT 64 Philips Medical Systems, Amsterdam, the Netherlands, with a 0.9 mmslice thickness and a 0.9 mm distance between slices. The pre-operative CBCT scans were then used to plan six experimental implants in each jaw model with the planning software (Implant 3D, Bionova, La Spezia, Italy) (Fig. 3, 4). The planning
data were exported to the CAD software program, where the surgical template were
designed using the same data as the planning software (Fig. 5).

After all implants had been placed according to the BioHorizons ModelGuide surgical protocol (Fig. 6), the jaws were again scanned with CBCT using the same image acquisition parameters and the same device (Fig. 7). Following the double scanning protocol, the images were sent back to the manufacturer of the surgical guide (Bionova) to overlay the images (Fig. 8,9,10,11). A software program was used to match pre- and post-operative implants positions. The following outcome variables were recorded:

1) Depth Deviation: The occluso-apical projection in millimetre of the postoperative implant axis on a plane through the pre-operative implant axis. This was measured at the level of the implant shoulder (D1 depth deviation), at the implant center level [6 mm apically, (D2 depth deviation)], and at the level of apical point (D3 depth deviation).

2) Radial deviation – the projection in millimetre, of the post-operative implant axis on a plane perpendicular to the pre-operative implant axis, measured at the level of the implant shoulder (SMR = shoulder mesial radial deviation, SDR = shoulder distal radial deviation) and at the level of apical point (ARP = apex radial deviation).

3) Angular deviation (AD) – the angle (as part of 360°) between pre- and post-operative implant axes.
Data Analysis

The \( t \) test was used to compare the D1, D2, D3 depth deviation, the SRM, SRD, ARP radial deviation, and the angular deviation. Statistical significance was defined as \( P<0.01 \).

Results:

Differences were observed between all measured distances (virtual versus actual). The D1 (at the level of the implant shoulder) distance had a mean value of 0.23 mm (SD 0.14). The D2 distance (at the level of implant center), and D3 distance (at the level of apical point) had mean values of 0.21 mm (SD 0.17) and 0.14 mm (SD 0.11), respectively. The mean apical point deviation was 0.15 mm (SD 0.29); while at the entry point the mean SMR and SDR radial deviations were 0.3 mm (SD 0.12), and 0.27 mm (SD 0.19), respectively. The mean angular deviation between the virtual and actual positions of twelve placed implants was 2.44 degrees (SD 1.98) (Table I). The maximum SMR error, the maximum SDR error, and the maximum horizontal apical error were 0.44 mm, 0.51mm, and 0.39 mm, respectively. The maximum vertical error was 0.25mm, while the maximum angle error was 5.61 degrees. Among the different positions, the difference were not statistically significant.
Discussion:

The literatures reporting accuracy of guided surgery have been recently reviewed and analyzed by some researchers (Jung et al. 2009, Schneider et al. 2009, Van Assche et al 2012), with the aim to summarize the available data. Van Assche et al. (2012), updating the previously systematic reviews on accuracy of computer-aided implant placement, reports nineteen studies which met the inclusion criteria. Meta analysis revealed a mean error of 0.99 mm (maximum 6.5 mm) at the entry point and of 1.24 mm (maximum 6.9 mm) at the apex. The mean angular deviation was 3.81 degrees (maximum 24.9° degrees). Because of different study designs (human versus cadaver or model, drill holes versus implants, different evaluation methods), it was not been possible to identify one system as superior or inferior to others. In general, the accuracy reported was better in studies with models and cadavers than in studies with humans. This can be explained by better access, better visual control of the axis of the osteotomy, no movement of the patient, and any saliva or blood in the preclinical models. Furthermore, there was no significant difference between cadavers and models; therefore, the influence of the material (bone versus acrylic) might be negligible for testing the accuracy in a preclinical model. To assess the accuracy of the implant systems the following parameters were selected: a) deviation error in a horizontal direction at the entry point of the drill or implant; b) deviation error in a horizontal direction at the apex of the drill or implant; c) deviation in height (vertical direction); d) deviation of the axis of the drill or implant (Vas Assche et al. (2012).

In the present study, these same parameters were evaluated by the same operator, using the same apparatus and setting. Because the same method of image acquisition was used preoperatively and postoperatively, any error in the methodology for making the surgical guide and overlapping images was minimized.
Few studies have been published documenting the in vitro accuracy of guided surgery on models. Sarment et al (2003) reported a mean entry error of 0.9mm (0.76-1.04), a mean apical error of 1.0mm (0.83-1.17), and a mean angular error of 4.5 degrees. Dreiseidler et al (2009) for the same parameters reported mean values of 0.2mm (0.15-0.21), 0.4mm (0.34-0.41, and 1.1 (1.0-1.28) degrees, respectively. Widman et al (2005), evaluating in vitro 56 sites, reported instead the only entry error mean value of 0.50mm (SD 0.30). In a vitro study conducted on polyurethane mandibles, Soares et al. (2012) evaluated the discrepancy between the virtual and actual implant position using digital processing image software. The mean entry deviation, the mean apical deviation, and the mean angular deviation were 1.39mm ± 0.4mm, 1.38mm ± 0.42mm, and 2.16 ± 0.91 degrees, respectively. In the present study we found lower values of discrepancy than these over-mentioned, as the mean entry error was 0.26 mm (SD 0.16), the mean apical error 0.15 mm (SD 0.29), and the mean angular error 2.44 degrees (SD 1.98).

In accuracy evaluation of 3D guided implant systems, it is important to evaluate the maximum deviation, which in vivo applications is crucial to prevent damage of anatomical structures. In the present study, the maximum apical point error was 0.25mm, while Sarment et al (2003) reported a maximum apical error of 1.6mm. The same parameter in the studies of Dreiseidler et al. (2009) and Soares et al. (2012) was of 0.62mm, and 0.71mm, respectively. All these studies presented more pronounced mean and maximum differences than were observed in the present study. The observed variations in the linear and angular measurements seem to be the results of more accurate positioning of the registration and surgical guides obtained in the present study by means of mini-implants, used as fiducial markers. The reproducibility of the template position during radiographic data acquisition and during implantation is a delicate issue, especially in edentulous patients. Many studies reported significantly better accuracy in partially edentulous patients than in totally edentulous patients, probably because the instability of the surgical template
(Fitzgerald et al. 2010, van Steenberghe et al. 2002, Hortwitz et al. 2009). Tahmasseb et al. (2009) previously described, in a case report of edentulous patient, the use of computer-aided three-dimensional planning protocol in combination with the placement of three mini-implants used as reference elements. Afterwards, the same group of researchers (Tahmasseb et al. 2011) evaluated in vitro the accuracy of this reference-based digital procedure. The mean misfit for all implants in the x-, y- a and z-axes was 0.026mm, 0.024mm and 0.01 mm respectively. The outcome of these studies suggested that the use of fiducial markers result in an high level of precision. The findings of our study confirm the data presented by Tahmasseb et al. (2009, 2011) and show that the use of three mini-implants, previously placed as reference elements, might improve the accuracy of the implant positioning after placement by guided surgery.

However, it must be remembered that the in vitro accuracy of guided surgery is not only depend by precise and stable repositioning of the registration and surgical template, but also by the sum of other cumulative error (Widmann & Bale 2005, Widmann et al. 2009 ) occurring during the image acquisition and data processing (Reddy et al. 1994), during the template CAD/CAM production (Van Steenberghe et al. 2002), and during the drilling phase, caused by the bur-cylindre gap, (Valente et al. 2009, and by attrition of sleeves and drills, after longer use (Horowitz et al. 2009). As it is crucial to understand the significance of each step, and to realize the magnitude of the cumulated inaccuracy, other studies are needed.

The accuracy of the method demonstrated in the present in vitro study is within acceptable limits for guided surgery described in the literature; however, caution should be exercised when extrapolating the results from the present in vitro study to clinical practice. Further research should involve clinical studies with long-term follow- up and strive for an improvement of the system and procedures regarding accuracy, predictability and reproducibility of implant placement as well as surgical and prosthetic outcomes.
Conclusions:
Considering the limitations of the present study, the *in vitro* investigated Implant 3D Computer Guided Implant System showed promising accuracy in virtual implant placement.
Bibliography:


Fig 1. Acrylic resin mandible covered with a silicone material to represent gingival tissue
Fig. 2. CT template screwed onto the mini-implants before the CBCT recording

Fig 3. Pre-operative CBCT scan used to plan six experimental implants in jaw model with the planning software
Fig. 4 Image of 3D Implant software, which creates 3D views for implant planning.
Fig. 5. Surgical template designed using the same data as the planning software
Fig. 6 Implants placed on acrylic model
Fig. 7. The model after implant placement, scanned with CBCT
Fig. 8 Distance Analysis
Fig. 9 Apical Point Distance Analysis
Fig. 10 Entry Point Distance Analysis
Fig. 11 Angles Analysis