Dynamic navigation: a prospective clinical trial to evaluate the accuracy of implant placement

Abstract

Aim: The objective of this prospective pilot clinical study was to evaluate the accuracy of a new dynamic navigation system and postoperative clinical outcomes.

Materials and methods: Ten patients were recruited and 18 implants were placed. The surgery was performed with the navigation system and according to the virtual planning. Ten implants were placed using a flapless technique and eight implant sites were prepared with a combined piezo-drill method. The deviation between the real implant position obtained from the postoperative cone beam computed tomography (CBCT) scan and the planned implant position was measured.

Result: The average deviation was $1.19 \pm 0.54$ mm. The mean deviation measured at the insertion point was $1.04 \pm 0.47$ mm and at the apical point it was $1.35 \pm 0.56$ mm. The depth error was $0.43 \pm 0.34$ mm. The axis deviation was $6.46 \pm 3.95$ degrees. No significant differences were found between the flapless and the open-flap approaches and between the conventional and piezoelectric techniques. No complications occurred.

Conclusion: The accuracy values reported in this study are comparable, although not superior, to the literature data regarding dynamic and static computer-guided surgery. Dynamic navigation could increase the quality and safety of interventions and may reduce morbidity when compared with freehand insertion techniques.

Keywords: computer-assisted surgery, image-guided surgery, implantology, navigation system, real-time tracking, implant placement accuracy

Introduction

Computer-assisted surgery has influenced the approach to most major and minor procedures in oral and maxillofacial surgery as well as in implantology. Drill guides are the most frequently used systems in implant surgery and have a mean accuracy of about 1.2 to 1.6 mm. However, use of drill guides is costly, particularly if only a small number of implants is required. Moreover, drill guides obscure the view of the surgical field and require longer drills that are more difficult to use. The time taken from the planning to the manufacture of the drill guide and the need for several laboratory steps represent further problems. These difficulties could be overcome by using three-dimensional (3D) printing. Dynamic navigation systems are used in computer-assisted surgery, particularly in neurosurgery, orthopaedic surgery, oral surgery, and maxillofacial surgery as well as in advanced implantology performed under general anesthesia as zygomatic implants. These systems have been used for several years, albeit infrequently because the reference tools designed for major surgery are unsuitable for procedures regularly performed under local anesthesia. Such navigation systems, together with dedicated software and tools for dental surgery and implantology, could overcome some of the limitations of drill guides. These navigation systems provide a direct view of the surgical site and allow the use of conventional drills; furthermore, they are fully digital, with no need for laboratory steps. Use of navigation systems in combination with ultrasonic instruments was recently proposed to optimize implant site preparation. However, there is little available data on the accuracy of these systems in daily practice used in conjunction with typical implant site preparation methods. Most published studies were performed in vitro and the majority of clinical studies are case reports. Few prospective or randomized clinical trials (RCTs) with ethics committee approval are currently available in the literature.

The aim of this pilot study was to evaluate the practicability, advantages, and disadvantages of using a new dynamic navigation system (ImplaNav; BresMedical, Sydney, Australia) in routine clinical practice. The data obtained will be employed for the setup of further studies with a larger number of patients. The primary objective of this study was to evaluate the accuracy of the system. The secondary objective was to evaluate the influence of the implant site preparation technique and the postoperative clinical outcomes and complications.
Materials and methods

A prospective pilot clinical trial was performed at the Oral and Maxillofacial Surgery Division, Department of Biomedical and Neuromotor Sciences (DIBINEM), University of Bologna, Italy, with the approval of the Sant’Orsola-Malpighi University Hospital (University of Bologna, Italy) Ethics Committee (20/2014/U/Disp). All the procedures were carried out in compliance with the ethical principles for medical research involving human subjects as stated in the Declaration of Helsinki.

Ten patients (seven female, three male) undergoing dental rehabilitation with at least one osseointegrated implant were recruited. Only implant sites without the need of bone grafting were included. All the patients were in good health, did not meet the exclusion criteria for dental implantology, and were treated according to the Helsinki Agreement (2013 version) regarding research on human subjects. All patients signed an informed consent form before being enrolled in the study. The mean patient age was 57 years (range: 38 to 69 years). Two patients were totally edentulous, and eight were partially edentulous.

In this study, the ImplaNav dynamic navigation system (Fig 1) was used, together with an intraoral reference tool. The study protocol involved the enrolment of 10 patients needing at least one implant for a fixed or overdenture prosthesis. All the patients followed the ImplaNav system protocol, which involves the positioning of a reference plate containing fiducial markers (markers plate [MP]) for calibrating the navigation system before undergoing cone beam computed tomography (CBCT) scanning. In the partially edentulous patients, a dental-supported MP, provided by the manufacturer, was fixed in position using a high-density impression material (Ramitec; 3M ESPE, USA). In the totally edentulous patients, a narrow implant of 3.25-mm diameter (MSc-IBNT; Southern Implants, Irene, South Africa) was used as a provisional implant and placed at the median point of the jaw under local anesthesia using a flapless method. The MP, containing the fiducial markers and a connection compatible with the provisional implant, was directly screwed onto the provisional implant. In all cases, a preoperative CBCT scan was performed with the MP in situ. The MP was then removed and replaced on the day of surgery. No differences in accuracy between the partial and totally edentulous protocols are declared by the navigation system manufacturer. Any difference was also reported by the operators during the clinical procedures. In one totally edentulous patient, a conventional radiographic template was positioned during the CBCT scan for the evaluation of the prosthetic emergence. In the other cases, fully digital planning was performed for the prosthetic assessment. Navigation system software was used in all cases for implant planning. For each site, the most suitable implant diameter and length were selected from the implant library. After completion of the virtual planning (Fig 2), the definitive implant surgery project was saved to disc.

On the day of surgery, the MP containing not only the fiducial markers but also a spherical connection for the navigation system reference tool was replaced in situ. Therefore, the patient reference tool (RTP) was fixed on that support. The second reference tool (RTh) was placed on the surgical handle through an adaptable joint for the contra-angle and the ultrasonic handpiece. Also, this specific joint presented a spherical connection for the navigation system reference tool. The use of a spherical connection supporting the reference tools allowed the surgeon to fix the navigation system camera in different positions in order to work comfortably with a direct view of both the surgical field and the navigation system screen; it followed the calibration of the navigation system, presenting the handle connected to the calibration tool tip to the navigation system camera. For the calibration of the drill tips, a connection reproducing the universal joint for the implant drill was embedded into the calibration tool. Then, the contra-angle handpiece was connected and exposed to the navigation system camera for about 3 s. This procedure allows the navigation system software to identify the drill position and axis. The next step was to con-
nect a lance drill of a known length memorized in the software. By touching the three markers on the MP, the position of the patient was identified. The following drills, already stored digitally in the software library, were selected without repeating the calibration procedure. A similar procedure was carried out for the ultrasonic tip, although this required the use of a specific connection into the calibration tool. The surgical procedure was performed according to the site-preparation instructions of the implant manufacturer. The virtual position of the drills and the implant placement were followed in real time on the navigation system screen (Figs 3 and 4). The surgeon could track the drill axis in three planes in real time, and monitor the planned implant position, the bone, and the anatomical structures around the implant site. Eighteen implants (16 IBT and 2 Co-axis; Southern Implants) were placed: nine each in the maxilla and mandible. Ten implants were placed using a flapless technique (four in the mandible and six in the maxilla) (Fig 5). In eight cases, during implant site preparation, the piezoelectric tips substituted the first drills according to the combined piezo-drill navigated implant site preparation technique. Only two implants showed transmucosal healing. In the other cases, implant exposure after 3 months preceded submerged healing. In one totally edentulous patient, the provisional implant for the supporting reference plate was used during the healing period for provisional mobile prosthesis retention through a Locator attachment (Zest Anchor Inc., Escondido, CA, USA) (Figs 6 and 7).

All patients underwent a CBCT scan at 3 months postsurgery to identify the positions of the fixtures. Due to the inclusion in the protocol of totally edentulous patients, a second CBCT scan was considered the most suitable procedure as

Fig 2 The preoperative virtual planning. The implant position is visualized on volume renderings and on cross-sectional, axial, and coronal images.

Fig 3 The real and virtual implant placement on the navigation system’s screen.

Fig 4 Implants placed with a minimally invasive and safe navigated flapless surgery procedure.

Fig 5 Provisional implant used to support the MP and retain of the provisional prostheses.
opposed to other methods not based on radiography (digital impression through scan abutment). In these edentulous patients, the bone alignment is considered the simplest way to achieve an accurate matching of the virtual planning with the postoperative data obtained by the CBCT scan. This issue was approved by the Ethics Committee. Fixture position was determined by the segmentation of the implant volume area acquired from the postoperative CBCT data using OpenMAF software.\(^6,7\) Next, the planned and actual positions of the implants were aligned (Fig 7) using Geomagic Studio software (version 12.0; Geomagic Inc., Morrisville, NC, USA) for surface analysis and for the measurement of deviation by a blind operator. The measurements of each implant were performed in two ways: First, all point-to-point distances were computed and used to calculate the average deviation. Second, the Euclidean distance between the 3D coordinates of the entry position and the apical point, as well as the deviation of the axis, was calculated for each pair of implants. The clinical outcomes and any complications were recorded.

A Wilcoxon rank sum test was used to evaluate the significance of differences in the accuracy of implant placement between the flap and flapless approaches and between the piezoelectric and conventional techniques. A linear regression model was used to evaluate the influence of implant length on placement accuracy.

### Results

The point-to-point distances of the 18 implants in the 10 patients had an average deviation of 1.19 ± 0.54 mm. The maximum deviation was 2.28 mm. A mean deviation of 1.04 ± 0.47 mm was found at the insertion point (range: 0.45 to 2.21 mm) and 1.35 ± 0.56 mm at the apical point (range: 0.59 to 2.28 mm).

Figure 8 illustrates the distribution of these linear deviations. The vertical deviation, ie, the difference in depth (z-axis) between the planned and the placed implant (absolute values) was 0.43 ± 0.34 mm (range: 0.03 to 1.41 mm). The axis deviation from the planned value was 6.46 ± 3.95 mm. All deviation values are shown in Table 1.

The deviation of implants placed using the flapless approach was 1.10 ± 0.58 mm at the insertion point and 1.27 ± 0.57 mm at the apical point (Table 2). The depth error was 0.49 ± 0.42 mm and the angular deviation was 5.28 ± 2.66 mm. Using the conventional open-flap technique, the errors were 0.96 ± 0.33 mm, 1.45 ± 0.60 mm, 0.35 ± 0.22 mm, and 7.93 ± 5.15 mm, respectively. The values of the two groups were not significantly different (\(P = 0.618, P = 0.724, P = 0.478\)). No differences were found in implant placement accuracy between the conventional and piezoelectric techniques (\(P > 0.05\)) (Table 3).

No significant correlation was found between implant length and accuracy of implant position, nor for linear error (\(R^2 = 0.03; P = 0.07\)) or angular deviation (\(R^2 = 0.10; P = 0.24\)). No intra- or postoperative complications occurred.

### Discussion

Accurate implant placement is essential for a successful prosthetic restoration and good functional and esthetic outcomes as well as to prevent damage to anatomical structures. Three-dimensional digital planning and computer-assisted
Table 1  Deviation values

<table>
<thead>
<tr>
<th></th>
<th>Deviation at the entry point (mm)</th>
<th>Deviation at the apex (mm)</th>
<th>Depth deviation (mm)</th>
<th>Angular deviation (degrees)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>1.04</td>
<td>1.35</td>
<td>0.43</td>
<td>6.46</td>
</tr>
<tr>
<td>SD</td>
<td>0.47</td>
<td>0.56</td>
<td>0.34</td>
<td>3.95</td>
</tr>
<tr>
<td>Maximum</td>
<td>2.21</td>
<td>2.28</td>
<td>1.41</td>
<td>6.46</td>
</tr>
<tr>
<td>Minimum</td>
<td>0.45</td>
<td>0.59</td>
<td>0.03</td>
<td>3.95</td>
</tr>
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</table>

Table 2  Deviation values using the flapless and open-flap approaches

<table>
<thead>
<tr>
<th></th>
<th>Deviation at the entry point (mm)</th>
<th>Deviation at the apex (mm)</th>
<th>Depth deviation (mm)</th>
<th>Angular deviation (degrees)</th>
</tr>
</thead>
<tbody>
<tr>
<td>OF</td>
<td>0.96 ± 0.33</td>
<td>1.45 ± 0.60</td>
<td>0.35 ± 0.22</td>
<td>7.93 ± 5.15</td>
</tr>
<tr>
<td>FL</td>
<td>1.10 ± 0.58</td>
<td>1.27 ± 0.57</td>
<td>0.49 ± 0.42</td>
<td>5.28 ± 2.60</td>
</tr>
</tbody>
</table>

Data are shown as mean ± SD
OF = open-flap surgery; FL = flapless surgery

Table 3  Deviation values using piezoelectric tips and conventional burs

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<thead>
<tr>
<th></th>
<th>Deviation at the entry point (mm)</th>
<th>Deviation at the apex (mm)</th>
<th>Depth deviation (mm)</th>
<th>Angular deviation (degrees)</th>
</tr>
</thead>
<tbody>
<tr>
<td>P</td>
<td>1.01 ± 0.25</td>
<td>1.37 ± 0.48</td>
<td>0.44 ± 0.26</td>
<td>7.63 ± 4.30</td>
</tr>
<tr>
<td>C</td>
<td>1.06 ± 0.62</td>
<td>1.34 ± 0.66</td>
<td>0.42 ± 0.41</td>
<td>5.52 ± 3.81</td>
</tr>
</tbody>
</table>

Data are shown as mean ± SD
P = piezoelectric tips; C = conventional burs
surgery methods have been developed to improve the accuracy of implant positioning. In vitro, ex vivo, and clinical comparative studies have shown that static computer-guided implant placement is more accurate than the freehand method and conventional surgical guides. In a RCT by Ver- cruysen et al, a static guidance system resulted in a significantly lower mean deviation at the entry point and at the apex, and a significantly lower angular deviation of the implant axis compared with freehand implant placement. Also, dynamic implant navigation increases the accuracy of implant placement compared with manual implantation, and shows no difference compared with static methods.

In vitro application of a navigation system can improve the accuracy of implant insertion. The majority of reports on the accuracy of dynamic navigation were in vitro and ex vivo studies; few were clinical studies. Almost all the clinical studies reporting the accuracy values of different navigation systems are case studies with a small sample size. Two of them used a flapless approach out of all of the cases.

This study is a phase II pilot study involving a group of patients treated with navigated surgery, some with a traditional open-flap approach and others with a flapless technique. The comparison between these methods indicates that the navigation system allows high levels of accuracy even in the case of a ‘blind’ and more challenging technique. Studies involving dynamic navigation with high-quality evidence are not yet present in the literature. RCTs have also not yet been performed, and only Block et al performed a controlled prospective cohort study with a considerable number of patients, showing a significant improvement of accuracy using a fully guided technique and a freehand method. The other studies involving a freehand control group are in vitro studies. More RCTs are required to compare the dynamic navigation technique with the conventional one in order to demonstrate the efficacy of this guided technique. Our study, as with other non-randomized studies, could not really control the selection bias. Nevertheless, we tried to prevent the detection bias by using a blind outcome assessor, and we reported the accuracy values in a similar way to the clinical results.

A single-arm prospective study by Wittwer et al reported a mean deviation between the preoperative plan and the postoperative position of 0.9 mm (0.0 to 3.4 mm) using a flapless approach. The same authors compared two navigation systems and reported mean deviations of 0.7 and 0.9 mm, respectively, and no intra- or postoperative complications. Wagner et al recorded a mean error of 1.1 mm (range: 0.0 to 3.5 mm); 0.9 mm at the base of the implant and 1.2 mm at the tip. The mean angular deviation was 6.41 mm (range: 0.41 to 17.41 mm). Block et al reported a mean angular deviation of 2.97 ± 2.09 degrees, a mean global platform position deviation of 1.16 ± 0.59 mm, a mean global apical position deviation of 1.29 ± 0.65 mm, and a mean apical depth deviation of 0.81 ± 0.06 mm.

In this study, the mean deviation was 1.19 ± 0.54 mm. The mean error at the insertion point was 1.04 ± 0.47 mm (range: 0.45 to 2.21 mm) and that at the apical point was 1.35 ± 0.56 mm (range: 0.59 to 2.28 mm). The depth deviation was 0.43 ± 0.34 mm, and the axis deviation from the planned value was 6.46 ± 3.95 mm. These values are comparable with other clinical, ex vivo studies involving dynamic navigation.

Studies of static guided surgery have reported similar outcomes. A recent meta-analysis of accuracy in static computer-guided implant surgery reported an overall mean deviation at the entry point of 0.99 mm (range: 0 to 6.5 mm) and a deviation of 1.24 mm (range: 0 to 6.9 mm) at the apex. The overall mean angulation was 3.81 degrees (range: 0 to 24.9 degrees) and the overall mean vertical deviation was 0.46 mm (range: -2.33 to 4.2 mm).

In this study, no intra- or postoperative complications occurred. Wittwer et al reported that when using a flapless approach, 2.5% of implants failed to osseointegrate, and 2.6% of cases showed bone fenestration. Few clinical studies have focused on complications in dynamic navigation, which hampers the evaluation of these issues. According to recent reviews, the use of a static guide can result in intraoperative and prosthetic complications. Schneider et al reported an early surgical complication rate of 2.5% at the implant level (9.1% at the patient level) due to limited access, necessity of bone augmentation, unexpected bony dehiscence, fracture of the template, and lack of primary stability. Some of these surgical complications are prevented by dynamic navigation because no template is required during surgery, and a direct view of the operative field is provided. In some cases in which we reported a deviation superior to 1.5 mm, this could have been due to a safe distance or an intraoperative correction of the implant site position where it was determined to be more adequate by the surgeon. This, in turn, was due to an incorrect virtual plan of the implant position. In fact, it is not always possible to perform a full comprehensive evaluation during the virtual planning due to issues such as soft tissue keratinization, bone hardness or areas in which the radiographic bone reconstruction does not replicate the clinical reality correctly. We did not treat these cases as complications, for two reasons: First, the vertical deviation, which we consider the most dangerous, never exceeded 1.5 mm. Sec-
ond, the surgeon was able to evaluate the deviation entity and the adjacent structures in real time. This allowed for the evaluation of whether or not the deviation could be considered acceptable. One of the advantages of dynamic navigation is the ability to modify the preoperative plan or the flap type during surgery because of the uninterrupted visualization of the anatomy of the implant site. In this study, seven implants were placed using a flapless approach. A computer-assisted system can assist in the management of this surgical technique. A disadvantage of flapless freehand surgery is that bone morphology cannot be observed, which leads to a risk of fenestration, bone dehiscence, and implant malposition. In this study, no difference was found between conventional flap and flapless approaches in terms of the accuracy of implant placement. Therefore, the use of a navigation system can overcome the drawback of a ‘blind’ technique and ensure a high level of accuracy.

In this study, eight implant sites were prepared using a mixed traditional/piezoelectric technique. Ultrasonic osteotomy improves the control of bone cutting, reducing the risk of damaging adjacent soft tissue and the generation of excessive heat. We used a mixed-site preparation technique, which involved the initial application of a piezoelectric tip followed by a conventional preparation. This enabled precise implant placement and was less time consuming than an ultrasonic protocol. This method was preferred by the surgeon in cases in which the ultrasonic tip facilitated maintenance of the planned implant trajectory. The accuracy of the implant position after preparation using the mixed-site preparation technique was similar to that using conventional burs.

The accuracy values reported in this study are comparable with the literature data regarding dynamic navigation. The dynamic navigation system showed a clinical accuracy similar to that reported previously using drill guides. The possibility of using the implant site preparation method preferred by the surgeon may facilitate the maintenance of the planned trajectory.

The high accuracy of dynamic navigated surgery is useful for dental implantology and could increase the quality and safety of interventions. Moreover, it may reduce the morbidity rate by increasing the frequency of flapless surgery. Other advantages are the possibility of modifying the preoperative virtual planning, the good perception of bone quality during drilling due to the freehand procedure, the direct view of the surgical field, the possibility of using it in case of reduced mouth opening, and the limited cost for each patient treated. Some disadvantages are the manual skill required, the learning curve influenced by the operator’s personal confidence with the computer and the 3D systems, and the initial cost of the device. Further clinical studies should evaluate the benefits of this technique, particularly in advanced implantology. Dynamic computer-guided surgery is a promising technology, and future development of the hardware and software could increase its relevance.

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References


Dynamische Navigation: eine prospektive klinische Studie zur Überprüfung der korrekten Implantatplatzierung

Schlüsselwörter: Computer-assistierte Chirurgie, bildgestützte Chirurgie, Implantologie, Navigationssystem, Echtzeitverfolgung, Präzision der Implantatplatzierung

Zusammenfassung

Das Ziel dieser prospektiven klinischen Pilotstudie war die Beurteilung der Präzision eines neuen dynamischen Navigationssystems und der postoperativen klinischen Ergebnisse.


Ergebnisse: Die durchschnittliche Abweichung betrug 1,19 ± 0,54 mm. Die mittlere Abweichung lag am Insertionspunkt bei 1,04 ± 0,47 mm und am apikalen Punkt bei 1,35 ± 0,56 mm. Der Tiefenfehler betrug 0,43 ± 0,34 mm und die Achsenabweichung 6,46° ± 3,95°. Sowohl zwischen dem lappenlosen und dem offenen Ansatz als auch zwischen der konventionellen und piezoelektrischen Präparationstechnik wurden keine signifikanten Unterschiede festgestellt. Es traten keine Komplikationen auf.


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