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Original Article

Accuracy and safety of real-time navigation during insertion of temporary anchorage devices - A randomized clinical trial

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KEYWORDS
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Temporary anchorage device (TAD)

Abstract *Background/purpose:* Temporary anchorage device (TAD) is one of the applications of dental implants that facilitate orthodontic treatment. However, there are possible complications in TAD surgery with the freehand technique. Navigation has been used in dental implantation with acceptable results. There has been no published study on the use of real-time navigation for TAD insertion.

Materials and methods: This was a split-mouth design randomized clinical trial in which the control group used a surgical guide (N = 16) for TAD insertion surgery and the experimental group used navigation for surgery (N = 16). We also performed a negative control by retrospective database survey to evaluate the freehand technique (N = 29). By comparing the platform center deviation and angular deviation of the control group, experimental group, and negative control, we can draw conclusions about the accuracy and safety of TAD insertion surgery using each method.

Results: The platform center deviation in the surgical guide group and the navigation group showed a statistical difference ($P < 0.05$), indicating that the surgical guide provided better position control. There was no statistical difference in terms of angular deviation.

Conclusion: The clinical use of real-time navigation in the insertion of TAD offers no more significant advantages than the freehand technique in terms of position and angular control. No immediate complications requiring implant removal occurred in this study. The combined technique has shown a trend in accuracy and safety, but a larger number of samples are still needed for statistical analysis to draw a definitive conclusion.

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Introduction

Real-time navigation is widely used in our lives. With the development of this technology, it has also been applied in the medical field.[1—4] In oral and maxillofacial surgery,[5] real-time navigation facilitates surgeons to treat facial trauma, resect midface and skull base tumors, or perform orthognathic surgery with good results.[6—20] The real-time navigation is also used in dental implant surgery.[21—28] The surgeon can perform virtual surgical planning in a short time. Real-time navigation enables the immediate adjustment of the surgical plan to different clinical situations. Real-time navigation can reduce the risk of complications and improve the quality of the result when dealing with difficult cases. In addition, this is a good tool for the new hand to learn new techniques.[29]

In recent comprehensive analyses, it has been shown that the average deviation of the central platform of implants assisted by real-time navigation systems for placement can reach up to 1.00 mm, with an average deviation at the implant apex of 1.33 mm, and an angular error of 3.7°. This achieves accuracy comparable to that of surgical guides in assisting with implants. With navigation system assistance, surgeons can visualize the horizontal position of the implant drill entering the surface directly, likely contributing to smaller deviations in the implant platform with navigation system assistance. Based on the inferred errors above, when using real-time navigation systems, the entry point of the implant should maintain a safety margin outside the implant radius of at least 0.5—1.0 mm, while the apex area should retain a safety margin of 1.2—1.7 mm to prevent damage to adjacent structures. Real-time navigation systems exhibit more variability in data distribution compared to surgical guides.[30]

Temporary anchorage device (TAD) is one of the applications of dental implants that must be placed in accordance with the orthodontic treatment plan to achieve the maximum effect.[31] When inserting TAD, damage to adjacent teeth and other vital structures must be avoided. Schulte-Geers et al. examined 1663 TADs with panoramic radiography and found that the percentage of direct contact with the root surface was 10.6 %; penetrating the root without causing pulp injury was 3.6 %; penetrating the root and causing pulp necrosis was 3.1 %.[32] A study by Alves et al. evaluated 4452 TADs and found that the probability of root injury was approximately 1.3 %, with one-third of these teeth requiring root canal treatment or extraction.[33,34]

No study has been found in the literature on this topic on the use of real-time navigation in the insertion of TADs. Therefore, this clinical study investigates the accuracy and safety of TAD insertion surgery using a real-time navigation protocol.

Materials and methods

This clinical trial was approved by the Research Committee of National Taiwan University Hospital (IRB case number: 20200115RINC). All participants in the experiment signed consent forms and were informed of their relevant rights and interests. It was a split-mouth design study in which the sample was signed as a control or experimental group, depending on the inclusion sequence. The process consists of three parts: preoperative preparation, TAD inclusion surgery, data processing, and analysis.

The patient was ordered to undergo a CBCT and received a CDICOM for planning. The control group was to undergo surgery using a surgical guide. The preoperative DICOM was imported into Mercury® (BenQ, Taipei, Taiwan) 3D implant planning and the surgical guide was 3D printed. The experimental group was operated with real-time navigation, and the DICOM was imported into the Implant Imaging System IRIS® (EPED, Taipei, Taiwan) for planning.

The control group underwent surgery using the surgical guide. After the preparation of the pilot hole, a TAD was inserted. The experimental group was assisted by real-time navigation in preparing the pilot hole, and then a TAD was also inserted. After completion of the bilateral surgery, a CBCT was obtained to assess the implant and to determine if any complications required immediate treatment. The negative control group was a retrospective analysis of TAD placed using the freehand method.

The postoperative CBCT DICOM was imported into Mercury® and rescheduled according to their ideal position. In the data analysis, we superimposed the planned position with the actual position to compare the implant platform center deviation and implant angular deviation.

Inclusion criteria:

1. Patients who underwent orthodontic treatment and TAD insertion surgery.
2. There was no contraindication for TAD insertion surgery.

Patients with the following conditions were excluded:

1. Obvious structural abnormalities make it unsuitable for navigation appliances and surgical guides.
2. Smoking, alcohol consumption, betel chewing.
3. Patients who, for any reason, are not suitable or willing to participate in this clinical trial.

Control group

The surgical guide design used in this study was Mercury®. First, select the area of the arch based on the 3D image. Place the simulated implant in the appropriate location and

define its radius, length and degree. Adjust the implant according to the adjacent teeth and vital structures. Once the design is ready, the surgical guide can be fabricated on a 3D printer.

The surgical guide must first be fitted so that it does not collide with the bracket. Ensure that the surgical guide is fully seated until all stoppers are exposed.

The preparation drill used for inserting the TAD was a 2.0 mm diameter dental implant drill.

According to the guidance, a guide hole was drilled approximately 5 mm deep into the cancellous bone. Saline was used to cool the bone and remove debris. The TAD is passively placed along the guide hole using the introducer (Fig. 1).

Experimental group

The real-time navigation used in this study was the Implant Imaging System IRIS®. First, select the area of the arch based on the 3D image. This step also creates several reference points on the tooth. Next, we place the implant on the arch according to the treatment plan, adjust its position and angle, and observe its relationship to the adjacent teeth and the mandibular canal.

The registration is divided into two parts: handpiece registration and patient registration. In handpiece registration, light and reflective devices are used so that the navigation system can detect the position of the handpiece and the length of the drill; before patient registration, the patient is asked to wear a specially designed tracker. During patient registration, the light and reflective device on the tracker is used so that the navigation system can detect the patient's position.

After the above steps are completed, the relationship between the handpiece and the patient is synchronously displayed on the computer system, the preparation of the guide hole is assisted by the real-time navigation, and the process is the same as the surgical guide procedure (Figs. 2 and 3).

Negative control

The purpose of establishing negative control in this study is to compare the freehand technique with the experimental and control groups. Using the negative control, we can determine whether inserting TAD using real-time navigation or surgical guides is more accurate or safer than freehand.

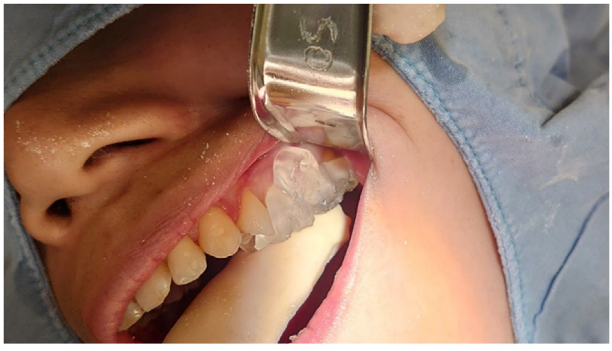

Figure 1 Surgical guide-assisted temporary anchorage device insertion.

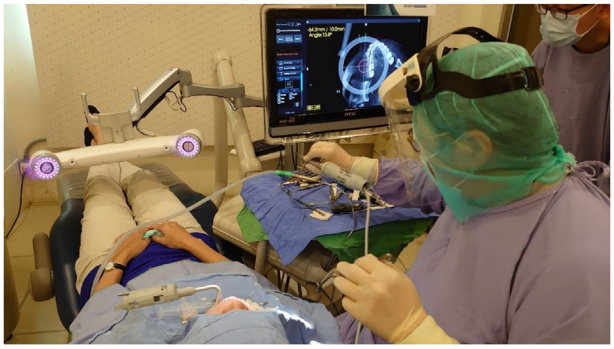

Figure 2 Real-time navigation assisted temporary anchorage device insertion.

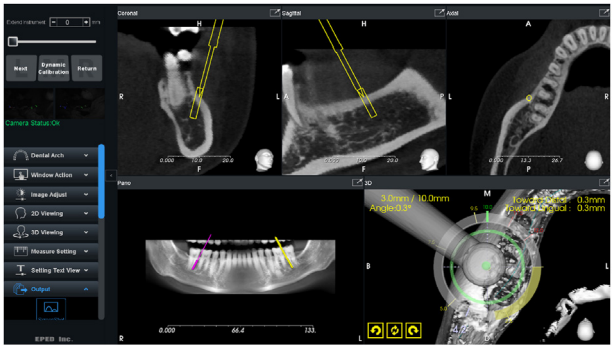

Figure 3 Navigation mode displaying the position and angle of the surgical drill.

The negative control was a retrospective study that searched the NTUH database for patients who previously underwent CBCT after TAD insertion. A total of 29 samples were enrolled as negative controls in the study. TAD planning was again based on the CBCT, according to the ideal position. Finally, the actual position was superimposed on the ideal position.

Data collection and analysis

Image analysis includes data and surgical outcomes analysis. In this study, the experimental group, control group, and negative control all used the Mercury® implant comparison for data analysis (Fig. 4).

The software has a spatial coordinate system. The center of the platform and the center of the implant tip have their spatial coordinates, which can then be calculated to get the implant's spatial vector. The distance between the two platforms can be calculated from the coordinates of the two implants, which can be considered the platform center deviation between the actual and the planned TADs.

The inner product is converted to the cosine function of the angle between the two vectors. After conversion to an inverse function, the angle between the two vectors is obtained, i.e. the intersection angle between the two implant axes, which can be regarded as the angular deviation between the actual and the planned TADs.

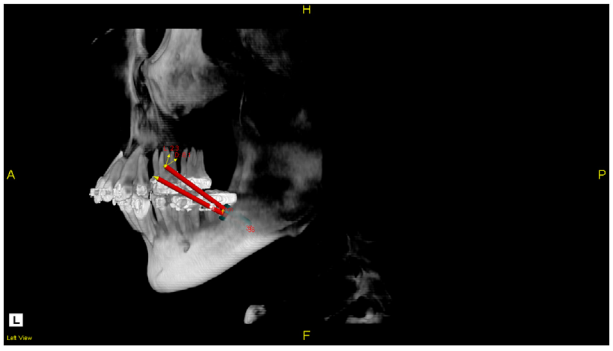

Figure 4 Comparison of the planned position and actual position of the temporary anchorage device.

The analysis of surgical outcomes includes the total time of planning, time for navigation registration, immediate complications (including injury to adjacent teeth, mandibular canal, soft tissue injury, and paresthesia, etc.), and long-term complications (including peri-implantitis, implant loosening, etc.).

Statistical method

Statistics should compare whether the platform center deviation and angular deviation are statistically significantly different between the experimental, control, and negative control ($P < 0.05$).

Results

Sample analysis

Since 2021, when compiling this article, 11 patients, including one male and 10 females, were included in this study. A total of 61 TADs were placed. The age distribution ranged from 16 to 42 years (mean age, 26.9 years). Both the experimental group and the control group consisted of 16 samples. Of these, 10 samples (62.5 %) were from the maxilla, and six (37.5 %) were from the mandible. Of these, 12 samples were operated during orthodontic treatment (75 %), and four were operated before treatment (25 %). Furthermore, an additional negative control group of 16 patients, with 29 samples with similar distribution enrolled as negative controls in the study.

Normality analysis

We analyzed the platform center deviation and angular deviation of 61 samples from the control group, experimental group, and negative control group. Normality analysis by Kolmogorov–Smirnov test and Shapiro–Wilks test. The platform center deviation was a non-normal distribution ($P < 0.05$), and the angular deviation was a normal distribution ($P > 0.05$). Because the samples were non-normal distributed, the Mann–Whitney U test was used, and a P value of less than 0.05 was determined to be statistically significant.

Comparison between the control group and the experimental group

For the platform center deviation, the minimum value of the control group was 0.3 mm, the maximum value was 2.8 mm, the mean value was 1.17 ± 0.77 mm, the median value was 0.9 mm. The minimum value of the experimental group was 0.3 mm, the maximum value was 6.8 mm, the mean value was 2.99 ± 1.75 mm, and the median value was 2.8 mm. The Mann–Whitney U test yielded a P value of 0.010 ($P < 0.05$), which reached statistical significance (Table 1).

For the angular deviation, the minimum value of the control group was 2.32°, and the maximum value was 29.59°, the mean value 12.43 ± 8.32°, the median value was 9.58°. The minimum value of the experimental group was 6.26°, the maximum value was 20.68°, the mean value was 12.49 ± 4.48°, the median value was 12.09°. The Mann–Whitney U test yielded a P value of 0.291 ($P > 0.05$), which did not reach statistical significance (Table 2).

Comparison between the control group and the negative control group

For the platform center deviation, the minimum value of the control group was 0.3 mm, the maximum value was 2.8 mm, the mean value was 1.17 ± 0.77 mm, the median value was 0.9 mm. The minimum value of the negative control group was 0.3 mm, the maximum value was 8.1 mm, the mean value was 3.10 ± 1.91 mm, the median value was 2.7 mm. The Mann–Whitney U test yielded a P value of 0.003 ($P > 0.05$), a statistically significant difference.

For the angular difference, the minimum value of the control group was 2.32°, the maximum value was 29.59°, the mean value was 12.43 ± 8.32°, the median value was

Table 1 Platform center deviation.

	Control group (n = 16)	Experimental group (n = 16)	Negative control (n = 29)
Min (mm)	0.3	0.9	0.3
Q1 (mm)	0.7	1.85	1.55
Mean ± SD (mm)	1.17 ± 0.77	2.99 ± 1.75	3.10 ± 1.91
Q3 (mm)	1.75	4.83	4.65
Max (mm)	2.8	6.8	8.1

mm, millimeters; Min, minimum; Q1, first quartile; SD, standard deviation; Q3, third quartile; Max, maximum.

Table 2 Angular deviation.

	Control group (n = 16)	Experimental group (n = 16)	Negative control (n = 29)
Min (°)	2.32	6.26	2.82
Q1 (°)	6.16	9.18	11.97
Mean ± SD (°)	12.43 ± 8.32	12.49 ± 4.48	15.64 ± 5.94
Q3 (°)	18.12	17.96	20.66
Max (°)	29.59	20.68	25.24

°, degree; Min, minimum; Q1, first quartile; SD, standard deviation; Q3, third quartile; Max, maximum.

9.58°. The minimum value of the negative control group was 2.82°, the maximum value was 25.24°, the mean value was 15.64 ± 5.94°, the median value was 16.56°. The Mann–Whitney U test yielded a *P* value of 0.084 ($P > 0.05$), which did not reach statistical significance.

Comparison between the experimental group and the negative group

For the platform center deviation, the minimum value of the experimental group was 0.3 mm, and the maximum value was 6.8 mm. The mean value was 2.99 ± 1.75 mm, the median value was 2.8 mm. The minimum value of the negative control group was 0.3 mm, the maximum value was 8.1 mm, the mean value was 3.10 ± 1.91 mm, the median value was 2.7 mm. The Mann–Whitney U test yielded a *P* value of 1.000 ($P < 0.05$), which did not reach statistical significance.

For the angular deviation, the minimum value of the experimental group was 6.26°, and the maximum value was 20.68°, the mean value was 12.49 ± 4.48°, the median value was 12.09°. The minimum value of the negative control group was 2.82°, the maximum value was 25.24°, the mean value was 15.64 ± 5.94°, the median value was 16.56°. The Mann–Whitney U test yielded a *P* value of 0.170 ($P > 0.05$), which did not reach statistical significance.

Discussion

This study indicates that real-time navigation is a reliable and safe tool, with no immediate or long-term complications reported in any of our cases. It represents a significant breakthrough in the limitations and blind spots of traditional techniques.

Upon reviewing the literature, this is the first clinical study to utilize a real-time navigation system to assist in the placement of TADs. The platform center deviation in the surgical guide group and the real-time navigation group showed a statistical difference, which means that the surgical guide was better than the real-time navigation in position control. The sample distribution of platform center deviation in the surgical guide group was relatively concentrated, which means that the surgical guide was much more consistent in controlling TAD position. There was no statistical difference between the surgical guide group and the real-time navigation group regarding angular deviation. The distribution of angular deviation in the surgical guide group was relatively scattered, while the distribution in the real-time navigation group was relatively concentrated, which means that real-time navigation was helpful for angular control.

Possible sources of error when using real-time navigation for TAD insertion surgery are registration point error, the stability of the navigation tracker, and human error. Since most patients who need to receive a TAD wear bracket that generate signal noise during CBCT taking, the 3D model created by the software will have inaccurate surfaces. The registration point selected during navigation may not correspond to the actual anatomical surface of the tooth. The stability of the navigation tracker depends on whether it can be stably adjusted to the target object. Since most cases are equipped with brackets, utility wax is used to prevent the appliance from deforming during the procedure (Fig. 5), which decreases the tracker's stability. The human error in using the navigation system is whether the operator is familiar with the system. Good hand-eye coordination must be maintained during the procedure.

To enhance the utility of real-time navigation, we propose the following improvement strategies: First, tracking light, replace the red light with a short-wavelength light to reduce physical inaccuracies associated with long-wavelength light. Second, sensor, increase the number or coverage area of sensor to minimize the chances of losing tracking. This can improve efficiency, enhance comfort, and reduce the risk of tracker detachment. Third, installation, integrate the navigation system into the chair to reduce the time required for transportation and to facilitate easier and more precise alignment of sensor and light with the target object.

Figure 5 Navigation tracker on dentition with orthodontic appliance.

Surgical navigation has been demonstrated to provide excellent accuracy in implant procedures. The entry point of the implant should maintain in safety margin outside the implant radius of at least 0.5—1.0 mm, while the apex should retain a safety margin of 1.2—1.7 mm to prevent damage to adjacent structures.[30]

However, the precision required for TADs placement exceeds that of dental implant procedures, particularly in the narrow safe zones in inter-radicular areas or in risky anatomy. Studies on the application of real-time navigation in dental implants cannot be directly applied to TAD. This study serves as a pioneering effort in this field; however, it is constrained by a limited sample size.

When surgeons manage cases with unique conditions —such as root proximity, abnormalities anatomy, or specific implant position, the clinical assistance tools, including surgical navigation, or surgical guides, can significantly reduce the risk of complications. These findings provide valuable guidance for the placement of TADs in the future.

A study comparing four surgical techniques, including manual, surgical guides, real-time navigation, and real-time navigation combined with surgical guides found that, in terms of apical deviation, vertical height deviation, and angular deviation, the combination of real-time navigation systems and surgical guides outperformed real-time navigation alone, which were superior to surgical guides alone. The manual method resulted in the highest level of error.[35] We also investigated the accuracy of using a combined approach of real-time navigation and surgical guides to assist in the placement of TADs. Preliminary data indicate that the combined method offers greater accuracy in controlling the platform and angulation compared to the real-time navigation system alone. While the combined approach demonstrates a trend toward enhanced precision, further studies with larger sample sizes are required to reach definitive conclusions.

Declaration of competing interest

The authors have no conflicts of interest relevant to this article.

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