

Accuracy of Dynamic Navigation Surgery in the Placement of Pterygoid Implants



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Pterygoid implant placement has not been a common treatment modality to manage the atrophic posterior maxilla. This randomized, controlled clinical trial evaluated the accuracy of dynamic navigation using trace registration (TR) technology in pterygoid implant placement when compared to free-hand surgery. Partially edentulous patients requiring at least one pterygoid implant to rehabilitate the atrophic posterior maxilla were included. Implant accuracy (in a prosthetically directed context) and the relation of the placed implants to the greater palatine canal (GPC) were evaluated using EvaluNav to compare the preoperative CBCT plan with the postoperative CBCT implant location. Osseointegration success, mucosal thickness, implant length, time spent for surgical placement, and ease of prosthetic restorability via degree of multi-unit abutment angulation were assessed. A total of 63 pterygoid implants were placed (31 using TR, 32 using free-hand) in 39 partially edentulous patients. Mean deviations between the planned and actual position for TR-placed implants were 0.66 mm at the coronal level, 1.13 mm at the apical level, 0.67 mm in depth, and 2.64 degrees of angular deviation, compared to 1.54 mm, 2.73 mm, 1.17 mm, and 12.49 degrees, respectively, for free-hand implants. In relation to the GPC, TR implants were more accurate when compared to the presurgical plan and took less surgical time. The mean mucosal thickness measured for all implants was 5.41 mm. Most implants were 15 to 18 mm long, and most prostheses (92%) could be accommodated by a 17- or 30-degree multi-unit screw-retained abutment. TR implants had greater short-term osseointegration success rates than free-hand implants (100% vs 93.75%). Pterygoid implant surgery can be a predictable and successful modality for prosthetically directed implant rehabilitation in the atrophic posterior maxilla, is more accurate than free-hand surgery, and takes less time when using dynamic navigation via TR. Int J Periodontics Restorative Dent 2020;40:825-834. doi: 10.11607/prd.4605

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The placement of dental implants in the posterior maxilla is challenging due to limitations in vertical bone height availability.1 This area also tends to have less favorable osseointegration success rates due to poor marrow quality, vascular potential, low bone density, and access difficulty.²⁻⁴ Limited vertical bone height in the posterior maxilla can be compensated for in several manners: sinus floor elevation (through a lateral window or crestal approach), pterygoid or zygomatic implants, and/or the use of short or ultrashort implants.^{5–16} Furthermore, stress distribution of force within the bone from occlusal loading is influenced by bone quality, the type of implant used (eg, diameter, length, macrostructure geometry), implant position, crown-to-implant length/ ratio, and the prosthetic design.¹⁷ The role of implant length seems to matter less for stress distribution; an exception is implants loaded in poor bone quality, where length does appear to be a more important factor affecting success rates.¹⁷

The use of pterygoid implants was introduced by Tulasne at the end of 1980s and involves one anatomical region but three different bones (the maxillary tuberosity, pterygoid process, and sphenoid bone). Although the use of pterygoid implants has been demonstrated to be a reasonable option,

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this procedure has not been widely used because of the proximity to vital structures, namely the greater palatine artery and pterygoid venous plexus, and the potential severity of complications with iatrogenic injury. Cadaveric studies presented in the literature demonstrate that the mean distance between the pterygomaxillary fissure and greater palatine canal (GPC) is 2.9 mm, with a minimum reported distance of only 0.2 mm. This infers that, in general, the use of pterygoid implants should be placed with a safety zone of ≥ 3 mm from such structures in order to comply with safe surgical practice.²⁰⁻²⁵

Today, the use of dynamic surgical navigation for planning and execution in implant surgery has demonstrated improved accuracy outcomes when compared to free-hand surgery. Moreover, the use of multi-unit abutments (MUA) to compensate prosthetically for angulation challenges allows the clinician to consider the pterygoid implant option as an alternative to sinus augmentation surgery or the use of short (or ultrashort) implants. 28,29

The aim of the present study was to evaluate the use of pterygoid implants (as an alternative to short implants or sinus bone grafting) placed using dynamic navigation surgery technology with trace registration (TR) in terms of accuracy as compared to implants placed via conventional free-hand surgery alone but treatment planned using CBCT imaging technology.

Material and Methods

A randomized, controlled clinical trial design was used and included patients who were partially edentulous in the maxilla or were about to be rendered edentulous (but had at least three stable teeth), and were to be rehabilitated with at least one pterygoid implant. Pterygoid implants placed in this study were either splinted to anterior implants and loaded immediately with a fixed prosthesis or loaded after 4 months if an immediate loading option was not possible. The placement of a pterygoid implant was performed either free-hand or using a dynamic navigation surgical system (Navident 2.0, ClaroNav) by random assignment at the time of surgery. If a patient needed two pterygoid implants (one per side), one side was performed free-hand and the other side was performed using the dynamic navigation surgical system. Patients were informed of the nature and potential risks of the proposed treatment and informed consent was reviewed and signed by each patient.

Postoperative CBCT scans were taken to assess the correct position and angulation of implants and the overall quality of the implant placement procedure using a proprietary low-dose imaging technology scan from OP 3D Pro (KaVo). The use of a postoperative CBCT scan was approved by the Ethics Committee of Sapienza, University of Rome (ref. 582/17).

The inclusion criterion for this study was a partially edentulous arch with sufficient bone to support implant placement (as determined by preoperative imaging and planning). Implants included in the analysis were placed from January to December of 2018 using the Trace and Place protocol for dynamic navigation surgery by one surgeon (L.V.S.). Patients with contraindications to elective dental implant surgery (ie, use of intravenous bisphosphonates, uncontrolled diabetes, use of drugs, irradiation in the head and neck area less than 1 year prior, presence of severe periodontitis) were excluded. All implants placed were Osseotite tapered implants (Zimmer Biomet).

The TR Protocol

The TR protocol has been previously published^{30,31} and consists of three steps: plan, trace, and place. The workflow has been described previously.^{30,31} Figures 1 to 8 demonstrate the treatment planning and dynamic navigation workflow.

Surgical Procedure

All surgery was performed by the primary author (L.V.S.). All patients were premedicated prior to surgery with either amoxicillin (2 g, 1 hour before implant surgery) or clindamycin if the patient had a penicillin allergy (600 mg, 1 hour prior to surgery). Each patient rinsed with 0.2% chlorhexidine mouthwash for 1 minute prior to the implantation procedure. Profound local anesthesia was achieved by infiltration using articaine with epinephrine (1:100,000).

Fig 1 Treatment plan of pterygoid implant therapy to reconstruct the maxillary right posterior region.

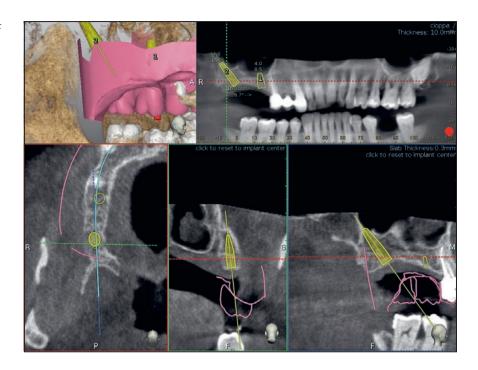




Fig 2 A jaw tracker was used in the mandible for the dynamic navigation Trace and Place protocol.



Fig 3 A head tracker was used in the maxilla for the dynamic navigation Trace and Place protocol.

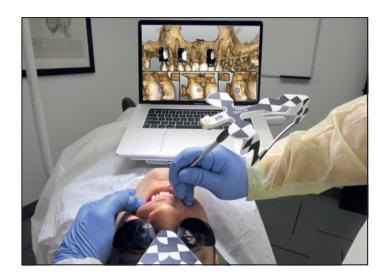


Fig 4 The tracing process is performed on the patient's corresponding teeth.

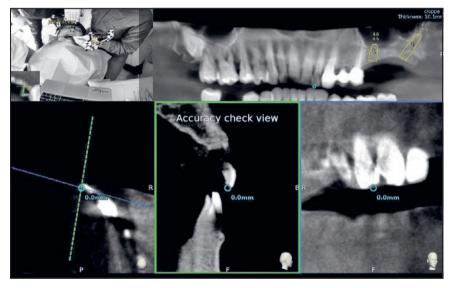
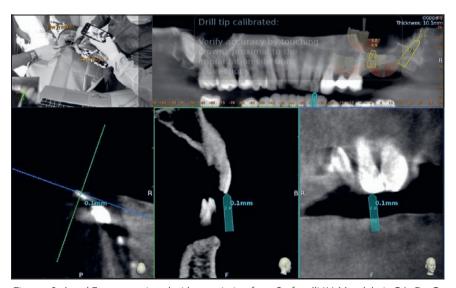
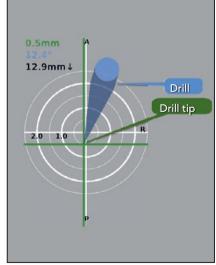


Fig 5 (left) The surgeon can then verify the registration accuracy by touching the tracer's ball tip on the patient's teeth from several aspects and comparing the physical location of the tip with its on-screen representation.

Fig 6 (below left) An accuracy check is performed by touching the tracer ball tip to the maxillary left lateral incisor, showing the accuracy of the dynamic navigation workflow.

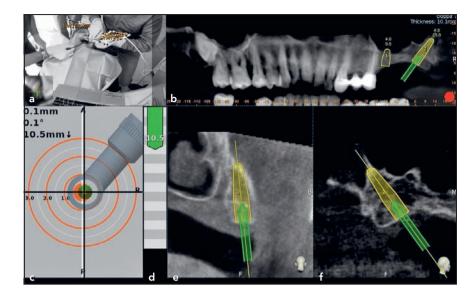
Fig 7 (below right) Target view that contains all of the information the clinician needs to guide the osteotomy and implant. The top value shown in the upper left corner is the distance between the drill tip and the central axis of the planned osteotomy; the middle vale is the angle between the drill and central axis of the planned osteotomy; the bottom value is the distance between the drill tip and the apical end of the planned osteotomy. A = patient's anterior; R = patient's right; P = patient's posterior.





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Fig 8 Several views are shown on the screen during surgery: (a) tracker video stream, (b) panoramic view, (c) target view, (d) depth indicator, (e) mesiodistal section view, and (f) buccolingual section view.



Surgery was initiated with a crestal incision in the tuberosity region, and minute flap elevation was performed to gain access to the bone. At that time, sequentially numbered envelopes that corresponded to the recruitment number of the patient obtained by computer-generated randomized numbers (prepared by the study advisor [N.P.]) were opened by a participant not directly involved in the surgery (U.G.), and the patient was treated according the outcome of the randomization assigned (freehand surgery alone or dynamic navigation). If a patient needed two pterygoid implants (one for each side), the implant osteotomy site preparation began on the patient's right side. According to the outcome of the randomization, each side was treated either by free-hand or with dynamic computer-guided navigation surgery. In the case of dynamic navigation surgery, a jaw tracker assembly was used for tracking in all cases.

Implant Placement

The osteotomy site was created using drills with increasing diameters to prepare the implant sites, as suggested by the manufacturer. Implants were inserted with a preset torque of 40 Ncm on the handpiece. The time to place the pterygoid implant was measured from the use of the first drill to the complete seating of the implant. Following placement, either straight or angulated MUA abutments were positioned on the implants, and the surgical field was closed.

Postsurgical Protocol

After surgery, each patient rinsed with 0.2% chlorhexidine mouthwash for 1 minute twice a day for 1 week. Patients were instructed to use ibuprofen (600 mg, bid to qid as needed) or paracetamol (1 g) for those patients allergic to nonsteroidal anti-

inflammatory drugs. Patients were instructed to follow a soft diet regimen for 2 weeks.

Placement Accuracy Evaluation

Following each surgery, the patient immediately underwent a postoperative CBCT scan. Using an accuracy evaluation application (EvaluNav) provided through the dynamic navigation system (Navident 2.0), the preoperative surgical plan and the postoperative CBCT were superimposed. This accuracy evaluation software has been validated and used in previous studies.^{27,30,31} Figure 9 demonstrates the planned and actual outcome of a pterygoid implant used in the study.

Statistical Analysis

A database was created using Microsoft Excel. Data were evaluated

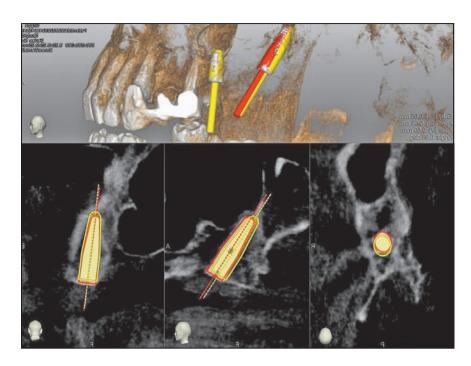


Fig 9 The planned (yellow) vs actual (red) EvaluNav outcome registration of the maxillary left pterygoid implant position using dynamic navigation.

using standard statistical analysis software (SPSS version 20.0, IBM). Descriptive statistics, including minimum, maximum, mean, and SD values, were calculated for each variable, and box plots were used to evaluate data outliers. Shapiro-Wilk test was used to determine whether the data conformed to a normal distribution. To identify statistically significant difference between the implant deviations by using dynamic navigation system or free-hand, independentsamples t test was used. In each test, the cut-off for statistical significance was $P \leq .05$.

Other data reported include the following:

- Angular values of the MUA used for the final prosthesis
- Mean distance between the virtual planned implants and the GPC

- Short-term osseointegration success of implants placed
- Length of time of surgical procedure
- Mean thickness of the transmucosal mucosa

Results

Partially edentulous patients (or ones who were about to become edentulous; n = 39) who had at least three stable teeth that could be used for TR were treated in this study. A total of 63 pterygoid implants were placed, 31 using dynamic navigation with TR and 32 using free-hand surgery alone, during a period from January 1, 2018, to December 31, 2018. All implants placed using dynamic navigation were performed using the TR protocol as described here.

Of the sample, 24 patients had bilateral pterygoid implants placed and 15 patients had unilateral pterygoid implants placed. The sample was divided and grouped via patients who were treated with the dynamic navigation system and patients treated with free-hand surgery alone.

Patient treatment characteristics and the total number of implant interventions in each group are reported in Appendix Table 1 (see quintpub.com/journals to view all Appendix Tables in the online version of this article).

Two implants inserted free-hand failed due to poor prosthetic positioning. One implant placed free-hand did not have adequate primary stability. It was immediately removed and replaced with an implant that had a wider diameter. All of the implants placed using dynamic naviga-

tion osseointegrated, as evaluated at the time of the impression for the final restoration (Appendix Table 2).

Mean accuracy of the pterygoid implants placed using dynamic navigation demonstrated a mean entry point deviation of 0.66 mm (coronal level), a mean apical deviation of 1.13 mm (apical 3D), and a mean apical depth deviation of 0.67 mm compared to the planned position. The mean angle discrepancy using dynamic navigation was 2.64 degrees (Appendix Table 3). The mean coronal, apical, and depth deviations and angular discrepancy of the pterygoid implants placed using freehand surgery alone were 1.54 mm, 2.73 mm, 1.17 mm, and 12.49 degrees, respectively (Appendix Table 3).

The difference between the distance of planned pterygoid implants to the GPC compared to the actual implant position ranged from –0.30 to 1.62 mm with a mean difference of 0.68 mm for dynamic navigation–placed implants and ranged from 0.12 to 3.05 mm with a mean distance of 1.46 mm for free-hand–placed implants. The mean mucosa thickness ranged from 2.50 to 9.40 mm with a mean thickness of 5.41 mm (Appendix Table 3).

The length of the pterygoid implants ranged between 11.5 to 20 mm, with the majority (81%) between 15 and 18 mm long (Appendix Table 4). Most angle corrections (92%) required a 17- or 30-degree MUA to accommodate the prosthesis (Appendix Table 5).

There were no outliers in the data, as assessed by inspection of box plots (Appendix Fig 1).

Independent-samples t test showed that the differences between the accuracy values of the two implant placement protocols demonstrated significantly different outcomes at all positions studied (coronal, apical, depth and angular deviations; Appendix Table 6).

When the pterygoid implant operation used dynamic navigation, the time of the surgical procedure averaged 9.3 minutes compared to 22.1 minutes when the case was performed with free-hand placement (Appendix Table 7). The difference in surgical time between the two groups (12.8 minutes) was statistically significant (P < .05, t test).

Discussion

The Glossary of Oral and Maxillofacial Implants defines the term "pterygoid implant" as "implant placement through the maxillary tuberosity and into the pterygoid plate."32 This definition is important because the term "pterygoid implant" is often used synonymously, but incorrectly, with "tuberosity implant," which involves only the maxillary tuberosity region and sometimes the pyramidal process of the palatine bone.33,34 Understanding this difference is important because the maxillary tuberosity is composed primarily of D3 to D4 bone quality. Comparatively, the area of pyramidal process of the palatine bone and the pterygoid process of the sphenoid bone is composed by D1 to D2 bone, implying higher potential success

rates as a result of better primary implant stability.³⁵

In a systematic review of the literature, Bidra and Huynh-Ba analyzed 897 pterygoid implants and reported that 70 implants failed before occlusal loading (92% survival rate) and 9 implants failed in the postloading phase.²² Candel et al reported similar success rates in a review of the rehabilitation of the atrophic posterior maxilla with pterygoid implants,23 and bone loss of pterygoid implants were comparable to those of conventional ones in their report. Araujo et al reported a 10-year survival rate of 94.85% for pterygoid implants and reported that most of the failures occurred after implant placements surgery but before occlusal loading.²⁴ This data is more consistent with the present findings reported in Appendix Table 2. In the present study, two implants that were placed free-hand failed whereas no implants placed under navigation failed. In this anatomical area where access is often difficult, having real-time verification and validation of positional accuracy can help (1) minimize over-preparing an osteotomy site and (2) optimize conditions for enhanced primary stability.

Rodriguez et al, analyzing 202 Caucasian patients via CBCT, reported that an 18-mm-long virtual pterygoid implant could be placed in 147 of the cases (72.8%), a 15-mm-long virtual pterygoid implant could be placed in 50 cases (24.7%), while a 13-mm-long virtual pterygoid implant could be placed in 5 cases (2.5%).²¹ In the present study, it was found that implant lengths of 15 and

18 mm could be placed in 81% of all patients evaluated (Appendix Table 4) and that 92% of the pterygoid implants placed could be managed with a 17- or 30-degree standard prosthetic MUA (Appendix Table 5). The other 8% required over 30 degrees of angle correction and necessitated customized componentry to correct the angle discrepancy. All implants were restorable, and all prostheses were screw-retained. While the present percentages are not exactly the same as that of Rodriguez et al, the trends are very similar for the length of implants used. This also underscores the need for personalized CBCT treatment planning and the value of image guidance for pterygoid implant therapy. The use of conventional MUAs in 92% of the present patients studied suggests that the pterygoid implant can be a reasonable treatment modality in delivering screwretained fixed prostheses without overcomplicating the prosthetic efforts in restoring such reconstructions.

What is striking in the present study is not so much the shortterm osseointegration success rate between pterygoid implants placed free-hand compared to those placed under dynamic navigation (93% vs 100%), but the difference between planned and actual entry point and apex positions as well as the difference in angle discrepancies (Appendix Table 3) in favor of dynamic-navigation surgery execution. In the present study, 31 pterygoid implants were placed using dynamic navigation with a mean angle discrepancy of 2.64 degrees

(range: 0.92 to 4.19 degrees) compared to the 32 pterygoid implants placed free-hand with a mean angle discrepancy of 12.49 degrees (range: 9.38 to 16.29 degrees). This difference between pterygoid implants placed either free-hand or via dynamic navigation is not only statistically significant, it is highly clinically significant, especially when one considers the range of error reported in each group. This trend was similar in the entry point and apex position of both groups (Appendix Table 3). In general, pterygoid implant-placement accuracy improved over 50% when the case was operated using dynamic navigation (entry point, apex depth, and apex 3D) and, from an anglediscrepancy standpoint, was nearly six times more accurate than freehand placement. To the authors' knowledge, this is the first study in the literature to compare pterygoid implant-placement accuracy using dynamic navigation compared to free-hand surgery.

One of the challenges of pterygoid implant placement is the proximity to vital structures and potential risk of iatrogenic injury to great vessels, which underscores the importance of accurate implant placement. Uchida et al, analyzing 78 CBCT scans of cadaveric Japanese patients, reported that the mean distance between virtually planned pterygoid implants and the GPC was 2.9 mm, with a minimum value of 0.2 mm and a maximum value of 6.9 mm.²⁰ All implants in the present study were planned with a 3-mm safety zone lateral to the GPC. The present study found mean distances

of 1.5 mm (range: 0.12 to 3.1 mm) and 0.68 mm (range: -0.30 to 1.5 mm) between the placed and planned pterygoid implants (relative to the GPC) when free-hand surgery alone was used compared to dynamic navigation surgery, respectively. The negative dynamic-navigation value means that the implant was medial to the planned implant position. Outcomes were more than twice as accurate when navigation surgery was used relative to the position of the GPC.

There are two different approaches to computer-aided implantology that have been developed to date: static and dynamic.²⁷ In the static approach, a custom drilling guide is digitally designed as part of the planning process and manufactured in advance of the surgery, typically by an external service facility using a stereolithographic printer. Vrielinck et al inserted 14 pterygoid implants using stereolithographically generated static surgical guides.²⁵ Four of the static-guided implants were lost, reportedly due to poor placement. The mean deviation between the planned pterygoid implants and the implants placed via a static quide was 3.57 mm (maximum reported deviation: 7.8 mm) at the entry point, 7.77 mm (maximum deviation: 16.1 mm) at the apex, and a mean angle discrepancy of 10.18 degrees (maximum deviation: 18 degreess) compared to the planned positions. The error was cited as a result of the last step of the procedure being carried out manually/ free-hand, despite the osteotomy site preparation being performed with a static guide. With pterygoid

implant surgery, the ability to use a static CT guide in a "totally guided" context (where the osteotomy site preparation and implant placement are "guided") presents a significant access limitation due to the regional anatomy and space required for predictable execution. There is also a relative loss of tactile sensation during the static-guided osteotomy site preparation, which may influence the surgeon to underprepare a site in an attempt to optimize primary stability during implant placement.

The present study found a significant advantage in using dynamic navigation for pterygoid implant surgery, not only in terms of the overall accuracy outcomes but also in the time it took to execute the surgery (22.1 minutes free-hand vs 9.3 minutes dynamic navigation). While there was a significant reduction in operating time when dynamic navigation surgery was employed, this may not have a significant impact on overall success.

The use of a second CBCT, taken postsurgery, in the present study exposed the patient to additional radiation to allow an accuracy analysis of planned vs actual implant positioning and relative to vital structures. A novel method to compare virtual and actual positioning of implant fixtures is the use of optical impressions via an intraoral scanner, eliminating the need for additional radiation exposure to the patient. Skjerven et al recently showed the accuracy of this method in guided implant placement.36 Because one of the present authors' objectives was to calculate the distance between the inserted implants and the GPC, a second CBCT was the only method that allowed them to do so.

Lastly, this study was limited in scope to a single surgeon in a single practice. Caution should be exercised when interpreting these results on a broader context and generalizing such results among surgeons. Additional similar in vivo accuracy studies should be undertaken to validate the results so that more data is available on a broader context in such a challenging yet important area. Such studies would further improve guidelines for pterygoid implant surgery protocols and optimize patient safety.

Conclusions

Pterygoid implant surgery can be a predictable and successful modality for prosthetically directed implant rehabilitation in the atrophic posterior maxilla. Pterygoid implant placement using dynamic navigation via TR is more accurate than free-hand surgery and takes less time.

Acknowledgments

The authors declare no conflicts of interest.

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Appendices

Appendix Table 1 Patients and Implant Treatment Groups					
	Patients, n	Implants, n			
Dynamic navigation	31	31			
Free-hand	32	32			
Total, n	39	63			

Some patients received more than one implant.

Implants were evaluated at the time of impression-taking for the final restoration.

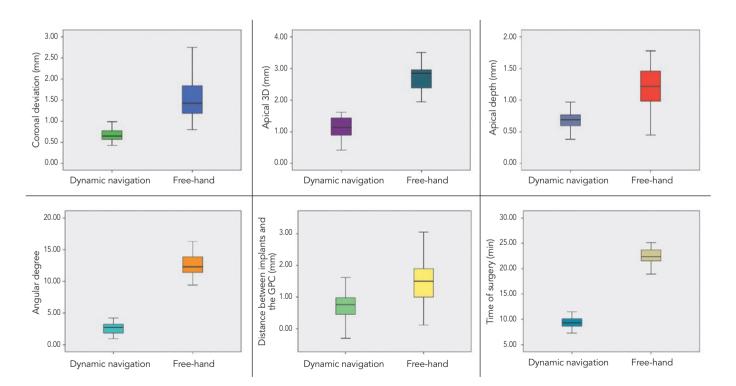
			al Inserted Implants 95% Cl				
	Mean (SE)	SD	Lower	Upper	Min	Max	
Coronal deviation, mm							
Dynamic navigation	0.6616 (0.02409)	0.13412	0.6124	0.7108	0.43	0.99	
Free-hand	1.5353 (0.09282)	0.52507	1.3460	1.7246	0.80	2.75	
Apical 3D, mm							
Dynamic navigation	1.1274 (0.06347)	0.35336	0.9978	1.2570	0.42	1.62	
Free-hand	2.7291 (0.06919)	0.39139	2.5879	2.8702	1.95	3.51	
Apical depth, mm							
Dynamic navigation	0.6690 (0.02719)	0.15138	0.6135	0.7246	0.33	0.97	
Free-hand	1.1706 (0.06791)	0.38414	1.0321	1.3091	0.45	1.78	
Angular degree							
Dynamic navigation	2.6361 (0.17325)	0.96464	2.2823	2.9900	0.92	4.19	
Free-hand	12.4859 (0.33030)	1.86848	11.8123	13.1596	9.38	16.29	
Distance between implants and the GPC, mm							
Dynamic navigation	0.6771 (0.08938)	0.49767	0.4946	0.8596	-0.30	1.62	
Free-hand	1.4616 (0.12582)	0.71173	1.2050	1.7182	0.12	3.05	
Time of surgery, min							
Dynamic navigation	9.3106 (0.16655)	0.92733	8.9705	9.6508	7.30	11.50	
Free-hand	22.4563 (0.31854)	1.80196	21.8066	23.1059	18.90	25.10	
Mucosa thickness, mm	5.4115 (0.20563)	1.60604	5.0001	5.8228	2.50	9.40	

SE = standard error; CI = confidence interval; GPC = greater palatine canal. There were 31 implants in the dynamic navigation group, and 32 implants in the free-hand group.

Appendix Table 4 Number of Different Implant Lengths Used					
Implant length, mm	n (%)				
11.5	10 (16%)				
15	34 (54%)				
18	17 (27%)				
20	2 (3%)				

Appendix Table 5 Number of Different MUAs Used					
Abutment/MUA angulation, degrees	n (%)				
17	20 (33%)				
30	36 (59%)				
> 30 (customized)	5 (8%)				

MUA = multi-unit abutment.



Appendix Fig 1 Box plots of the assessed parameters for both groups. Boxes contain 50% of all values. The horizontal lines inside the boxes indicate the medians. The vertical lines extend to $1.5 \times$ interquartile range.

Appendix Table 6 Independent t Test Results Showing the Difference in Accuracy of the Final Implant Results Between the Two Groups

	Independent t test for equality of means						
					95%	95% CI	
	t	df	Р	Mean	SE	Lower	Upper
Coronal deviation, mm	- 9.111	35.151	.000	-0.87370	0.09589	-1.06835	-0.67905
Apical 3D, mm	-17.031	61.000	.000	-1.60164	0.09404	-1.78969	-1.41359
Apical depth, mm	-6.857	40.656	.000	-0.50159	0.07315	-0.64936	-0.35383
Angular degree	-26.408	46.748	.000	-9.84981	0.37298	-10.60026	-9.09935
Distance between implants and the GPC, mm	-5.055	61.000	.000	-0.78447	0.15519	-1.09479	-0.47414
Time of surgery, min	-36.571	46.663	.000	-13.14560	0.35946	-13.86888	-12.42233

SE = standard error; CI = confidence interval; GPC = greater palatine canal.

Appendix Table 7 Descriptive Statistics of the Total Surgical Time (in Minutes) for Both Groups						
	Mean	SD	Min	Max		
Dynamic navigation	9.3	1.13	7.3	12.3		
Free-hand	22.1	2.10	17.9	25.1		