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Accuracy of dental implant placement via dynamic navigation or the freehand method: A split-mouth randomized controlled clinical trial

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Abstract

Objectives: The aim of this split-mouth randomized controlled clinical trial was to compare the deviations of planned and placed implants placed by the assistance of a micron tracker-based dynamic navigation device or freehand methods.

Material and methods: A thermoplastic fiducial marker was adapted on the anterior teeth, and cone-beam computerized tomography was used for imaging. A minimum of one implant was planned for each side of the posterior maxilla, and the dynamic navigation device or freehand method was randomly used for surgical insertion. Deviations were measured by matching the planning data with a final CBCT image. Linear deviations (mm) between the planned and placed implants were the primary outcome. The results were analysed by generalized linear mixed models ($p < .05$). (NCT03471208).

Results: A total of 92 implants were placed to 32 volunteers, and 86 implants were included in the final analysis. For the linear deviations, mean of differences (Δ) was 0.72mm (Standard deviation (*SD*): 0.26); (95% Confidence interval (CI): 0.39–1.02) in the shoulder of the implants ($p < .001$) and 0.69mm (*SD*: 0.36); (95% CI: 0.19–1.19) in the tip of the implants ($p < .001$). For the angular deviations, Δ was 5.33° (*SD*: 1.63); (95% CI: 7.17–3.48); ($p < .001$).

Conclusions: The navigation technique can be used to transfer virtual implant planning to the patient's jaw with increased accuracy.

KEYWORDS

clinical trial, computer-assisted, computers, dental implants, dimensional measurement accuracy, surgery, tomography

1 | INTRODUCTION

Despite the widespread use of dental implants in all types of edentulism, poor outcomes due to suboptimal positioning of the fixture body are not scarce (Arisan, Karabuda, Mumcu, & Ozdemir, 2013). The consequences of an implant body malposition may become evident in the short- and late-term and are not remediable without the removal of the implant in many instances. Various types of custom-made surgical guides were introduced for the prevention of such problems (D'Haese, Ackhurst, Wismeijer, De Bruyn, & Tahmaseb, 2017). Accuracy in the transfer of the virtual, prosthetically driven planning to the patient's jaw was further improved via

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the introduction of static CAD/CAM-based rapid prototyping technologies known as stereolithography (Vercruyssen et al., 2015).

Production and delivery of static guides are, however, subject to additional time and costs, foreclosing their feasibility in busy practices (Sanz et al., 2015). Dynamic navigation devices derived from frameless stereotactic surgery units are employed in clinical neurosurgery with a high success (Guo et al., 2018). Simplified setups developed for oral implantology are being launched that allow planning and execution of virtual surgery without the need of a static guide (Herklotz, Beuer, Kunz, Hildebrand, & Happe, 2017). Amongst the available navigation instruments, the micron tracking technology stands out given its smaller dimension, high accuracy and reduced overall cost (Reaungamornrat et al., 2012). Thanks to the increasing power of the microprocessors, video-optical trackers are capable of generating precise congruency of CBCT-based virtual implant planning with the spatial positions of the markers attached on the surgical handpiece and the patient's relevant anatomic structure. However, the clinical accuracy of this methodology in the transfer of virtual implant planning to the patient's jaw is generally limited to case reports. Inter-individual variability in such reports can be addressed by split-mouth designs (Lesaffre, Philstrom, Needleman, & Worthington, 2009). The aim of this study was to compare the deviations of planned and placed implants placed by dynamic navigation or freehand techniques.

2 | MATERIAL AND METHODS

2.1 | Calculation of the sample size

Due to the lack of sufficient studies suitable for the representation of a valid sample, mean linear deviation values in the shoulder of the implants reported in previous similar studies (Arisan, Karabuda, Piskin, & Ozdemir, 2013; Casap, Wexler, Persky, Schneider, & Lustmann, 2004; Vercruyssen et al., 2015) were referenced, and commercial software (GPower, Dusseldorf, Germany) was used for the estimation of the required sample. As a requirement of the ethical committee, the calculation was performed on the implant level and a minimum n of 86.1 implants were calculated to detect 30% linear deviation difference between the shoulders of the test (dynamic navigation-assisted implant surgery) and control groups (conventional freehand implant surgery) at $\alpha = 0.05$ with 80% statistical power. A final goal 90 implants distributed on 32 patients was set considering the possible dropouts and failures.

2.2 | Ethical approval

The study was approved by the local ethical committee (04.11.2015/71306642-050.01.04-) and conducted in accordance with the Helsinki Declaration of 1975 as revised in 2013. To test the null hypothesis, implants placed by the assistance of the stereotactic navigation device or the freehand technique are not associated with a statistically significant difference regarding deviations between the planned and placed implants; a clinical trial including within-subject randomization (split-mouth) was conducted (NCT03471208).

2.3 | Recruitment of the volunteers and inclusion/exclusion criteria

Between November 2015 and January 2018, 87 volunteers who sought tooth loss treatment at the Department of Oral Implantology, Faculty of Dentistry, Istanbul University considered to participate and they assessed for eligibility. All volunteers were initially evaluated by a panoramic X-ray following an oral examination. Patients aged 18 years or older with bilateral edentulism in the posterior maxilla (Kennedy class I (Kennedy, 1960) and showing a sufficient amount of bone volume to receive at least one standard 3.5-mm diameter and 10-mm length implant fixture either side of the maxilla (corresponding to a minimum of 2 implants per patient) were included. Patients missing more than two maxillary incisor teeth, unsuitable anatomic or dental conditions for sufficient support and stabilization of the dynamic navigation devices' thermoplastic stent, insufficient volume of bone precluding the receipt of a 3.5-mm diameter and 10-mm length implant fixture in any side of the posterior maxillae and any local and/or systemic condition hindering dental implant surgery were excluded. Patients smoking > 5 cigarettes per day were also not included. All volunteers provided written consent approving participation in this study.

2.4 | Thermoplastic radiopaque stent

A thermoplastic radiopaque stent was used for the dynamic registration and tracking of the patient tomographic data in relation with the planned implant positions and the surgical handpiece. The radiopaque component of the stent is embedded into a thermoplastic component designed to cover the teeth surface. The stent was placed in hot water for 2 min. The softened material was carefully adjusted onto the existing teeth in the anterior maxilla. A sponge and cold-water spray were used for adaptation onto the teeth surface while allowing the material to harden and set. The stent was removed, checked, and firm adaptation and stability were necessary because the exact tomographic location was going to be mapped by the software via the fiducial tag designed to be screwed onto this stent.

2.5 | Imaging and software planning

All patients were scanned with the prepared radiographic stents by the same CBCT device (I-CAT, Imaging Science International, Hatfield, PA, USA) using a standard exposure parameter (170x 230-mm FOV, 120 kVp and 18.7 mAs). Obtained data were loaded to a personal computer (MacBook Air 2015, Apple, California, USA) to which the navigation

software (Navident, ClaroNav, Toronto, Canada) was installed. The radiographic object was detected automatically by the software, yielding accurate mapping coordination of the patient bone anatomy. All virtual implant planning steps were performed jointly by two surgeons (CA and VA) with a minimum three-year experience in guided implant planning and placement. A custom panoramic curve was adjusted, and images were reformatted by the software for easier implant planning along the edentulous curve. Appropriate virtual positioning of a 3.5-mm diameter and 10-mm length cylinder body was established on the axial, sagittal and frontal views referring the virtual crowns provided by the software. All virtual implants (n = 92) were positioned at the equicrestal level and along the axis of the relevant missing teeth.

2.6 | Randomization

In all patients, a minimum of one implant was previously planned for the right and left side of the maxilla. Block randomization was refrained to allow intra-operative flexibility in case of a complication or technical event precluding further progress of the procedures. Randomization of the navigation assistance or freehand techniques was determined according the flip of a coin for each implant. When multiple was determined according the flip of a coin for each implant. When multiple implants were planned for any side of a patient, the last implant in that side was not randomized and included in the other group such that both techniques were applied in the same side and patient. Consistent with the learning-curve analysis requirements, another coin was tossed to decide the side of the jaw (left or right maxilla) to begin the surgery. Until the stage of randomization, allocation of techniques to any of the implants was unknown by the patient and the surgeon. After this stage, concealment of the allocation or blinding was no more possible.

2.7 | Surgery

All surgeries were performed by a surgeon (VA) with a strong experience of conventional and guided implant surgery techniques. Before the study, the surgeon used 4 phantom models for training and planned and placed 10 implants to 4 patients via the dynamic navigation device assistance. Prior to surgery initiation, the mouth opening was measured by a calliper to determine the maximum distance between the upper and lower central incised margins.

Local infiltration anaesthesia was established, and a small mid-crestal incision was performed for visualization of the recipient bone. All osteotomies were completed by 3 drills consisting of a pointed-pilot, twist and final shapes, which were provided in the surgical tray of the employed implant system.

In the freehand group, osteotomy was accomplished manually according the established protocol by Branemark and co-workers (Branemark, Zarb, & Albrektsson, 1985). No computer assistance or guide was used except the virtual planning displayed on the computer screen. Care was given to comply with the virtual positions of the implants manually. Forty-five implants were placed accordingly by the handpiece-driven implant mount provided in the surgical tray. In all patients, all of the planned implants were inserted in a single surgical session. An equicrestal shoulder level was sustained for all implants in the freehand group.

In the navigation group (corresponding to the opposite side of the quadrant), an oral implantology-dedicated navigation system based on the micron tacking technology (Reaungamornrat et al., 2012) employing two stereoscopic cameras was utilized (Navident, ClaroNav, Ontario Canada). Cameras trace the motion of the fiducial tags on the patient (attached onto the thermoplastic stent) and the surgical handpiece, which dynamically interacts with the software processing the CBCT-based planning data. The radiographic stent was mounted on the patient's existing teeth, and the fiducial tag with the black & white markings were screwed. A similar fiducial tag was also attached firmly onto the surgical handpiece. The software (Navident v 1.3: Ontario, Canada) recognizes both tags and proceeds to a short calibration procedure prior to the use of the handpiece and different length of osteotomy drills. Osteotomy was accomplished via the help of a crosshair sign on the computer screen representing the circular centre point of the implant shoulder (entry point). Osteotomy depth is shown by a bar next to the target sign. A 3D figure also assisted in procurement of the drill angulation. To achieve the highest possible accuracy, implants (n = 47) were calibrated like a drill and placed according to the depth and crosshair indicators on the software screen.

In both groups, standard root shaped implants (Southern Implants, Cape Town, South Africa) of identical size (3.5-mm diameter and 10-mm length) were used. Closure screws were mounted, and the flap was repositioned by two intermittent 3.0 silk sutures. Sutures were removed after one week. After 3 months, all patients were rescanned by the same CBCT machine with the initial exposure parameters.

2.8 | Evaluation of accuracy

DICOM data obtained at the end of the 3-month healing period were loaded to software designed for measuring the deviations between the planned and placed implants (EvaluNav, Toronto, Canada). Automatic matching that referred the identical anatomy was used unless any mismatch was observed and corrected manually. In all patients and all implants, planned and placed implants are automatically isolated by the software. Centre points in the tip and the shoulder of the implants were marked and connected by a virtual line representing the axis. Deviations between the planned and placed implants (distance between the circle centre of the implant shoulder, tip and the angular deviation between axes of the implants) were calculated according to the previously established methodology (Arisan, Karabuda, & Ozdemir, 2010; Arisan, Karabuda, Piskin, et al., 2013), employing coordinates automatically provided by the software (Figure 1). Measurement processes were undertaken by an individual (Dental assistant A. Atasoy) unaware of the patients and the techniques. Previous training and calibration of the examiner

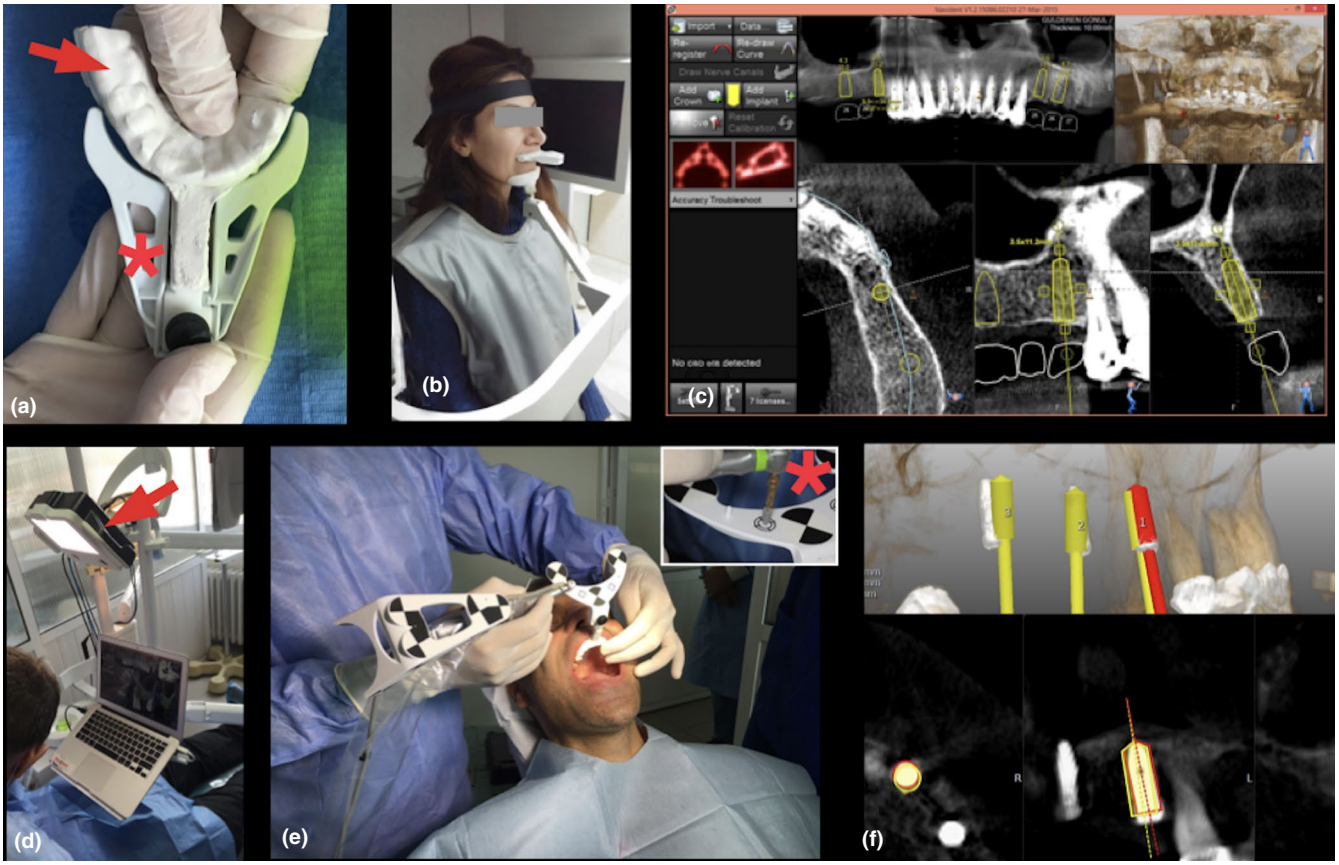

FIGURE 1 Clinical stages of treatment in the navigation group and deviation measurement in the groups. (a) Prepared thermoplastic stent (arrow) connected to a radiopaque mark (asterix); (Navistent, Claronav, Toronto, Canada). (b) CBCT imaging of the patient with the stent. (c) Planning of the implants in the dedicated navigation software. (d) Clinical setup of the dynamic navigation device (Navident, Claronav, Toronto, Canada) incorporating micron tracking sensors (arrow) and a laptop computer running dedicated software (Navident, Claronav, Toronto, Canada). (e) Identification and calibration of the surgical handpiece and the patient's jaw was accomplished by the black-white-printed fiducial markers. Appropriate depth control was sustained by the software calibration of the implant body (asterix). (e) Matching of the planning data with the post-op tomography and measurement of the deviations between the planned and placed implants on special software (Evalunav, Claronav, Toronto, Canada)

was performed using two previous patient data. Planning data were matched by the post-op CBCT, and the amount of deviations were measured by AA. Same process was performed by VA with an experience of such measurements in previous studies (Arisan et al., 2010 and Arisan, Karabuda, Mumcu, et al., 2013). An acceptable *inter-examiner* calibration was achieved following the clarification of some virtues between the examiners (r = .88; p = .84, r = .75; p = .69 and r = .71; p = .66 for the shoulder, tip and angle deviation measurements, respectively). Same measurement procedures were repeated on three separate days and thanks to the use of the aforementioned automatic matching software; a high *intra-examiner* reliability was confirmed (r = .84; p = .41, r = .64; p = .39 and r = .59, p = .21 for the shoulder, tip and angle deviation measurements, respectively).

2.9 | Statistical analysis

Linear deviations (mm) between the planned and placed implants were the primary outcome variable and the angular deviations (°) between the planned and placed implants, effect of mouth opening (mm), the side of application (right or left side of the maxilla) on the deviation rates and the learning curve (reduce trend of the deviation values in the consecutive patients) were the secondary outcome variables. Observational findings were also recorded.

Descriptive statistics, including mean, standard deviation, range (minimum–maximum) and 95% confidence intervals (CI), were calculated. The Shapiro–Silk test was used for confirmation of the normal data distribution. Implants clustering on the same patient's jaw are subject to the same confounding factors and therefore cannot be accepted as independent. Accordingly, pairwise comparisons disregarding the dependency of the implants in the same patient were not used. A generalized linear mixed model was adapted with deviation values as dependent variables. Group variables (navigation of freehand) were included as fixed effects, and volunteers were included as the random effect. Learning curve was analysed on multilevel regression models employing the linear and angular deviations as a continuous predictor. Gamma-distributed generalized linear regression models were used to predict the slope and intercept of

the sequential linear and angular deviation measurements (random effect) on the consecutive patient order for the group variables (fixed effect). Categorical data were analysed by the Pearson chi-square test and the Fisher's exact test. Correlation of the patients' mouth opening and relevant deviation values were also tested by the Spearman test. NCSS (Number Cruncher Statistical System 2007, Kaysville, Utah, USA) statistical software was used for all statistical analyses. Any probability level (*p*) greater than 95% was accepted as statistically significant. The manuscript was prepared according to the CONSORT guidelines.

3 | RESULTS

Thirty-two patients (25 females and seven males) were recruited for this study. The mean age of the patient group was 48.4 (range: 21 to 78) years.

Intra-oral adaptation of the radiopaque stent was challenging in some patients and was repeated due to the lack of sufficient stability after the setting of the thermoplastic retentive material. Despite these attempts, the stability of the radiopaque stent during the surgery was not satisfactory in two patients. The surgery was not performed, and a complete pre-op. preparation process was repeated for these patients. There were no other complications and problems encountered during the surgery in any groups. Initial engagement to the patient's jaw and the relevant osteotomy procedure were unfamiliar to the surgeon given that the crosshair sign was viewed on the monitor rather than directly observing the patient's jaw for osteotomy in the navigation group. This feature resulted in frequent starts and stops while confirming a proper osteotomy and sustaining accuracy via the software screen. The familiarity and ease of application of the navigation device for the osteotomy increased in subsequent cases.

All 92 implants were placed as planned. There were no implant failures during the course of this study, yielding a 100% early term implant success rate. During the healing phase, one patient relocated to another country, and one patient refused to undergo to a second CBCT exposure due to anxiety related from a recent oncologic diagnosis. These two patients' data were removed from the study, and a total of 30 patients and 86 implants (n = 43 in each groups) were included in the final analysis (Figure 2).

There were no extreme deviations or collision with any critical anatomy in any patient. The effect of group variable was statistically significant for the differences of the linear deviation values at the shoulder (F: 26.132, p < .001) and the tip region (F: 11.138, p < .001). Mean linear deviations at the shoulder of the planned and placed implants were 1.70 mm (*SD*: 0.13) and 1.01 mm (*SD*: 0.07) for the freehand and navigation groups, respectively (mean of Δ: 0.72mm (*SD*: 0.26); (95% CI: 0.39–1.02). Mean linear deviation at the tip of planned and placed implants were 2.51 mm (*SD*: 0.21) and 1.83 mm (*SD*: 0.12) for the freehand and navigation groups, respectively (mean of Δ: 0.69 mm (*SD*: 0.36); (95% CI: 0.19–1.19). The differences in linear deviations between the groups were statistically significant for both the shoulder (F: 26.132, p < .001) and the tip regions (F: 11.138, p:.001). Mean angular deviations were 10.04° (*SD*: 0.83) and 5.59° (*SD*: 0.39) for the freehand and navigation groups, respectively (mean of Δ: 5.33° (*SD*: 1.63); (95% CI: 7.17–3.48), and the differences were statistically significant (F: 27.746, p < .001); (Figure 3; Table 1). Maximum deviation values akin to 1 cm were observed in the freehand group, whereas such values were less than 0.5 cm in the navigation group.

Linear and angular deviation values in the right and left side of the maxilla were not statistically significant for the navigation group (p = .89). However, statistically significant linear deviation differences were detected in the freehand group at the shoulder (2.19 mm [*SD*: 0.25] and 1.44 mm [*SD*: 0.22]; (mean of Δ: 0.51mm (*SD*: 0.2); (95% CI: 0.78–0.31);) p = .022) and the tip (3.20 mm [*SD*: 0.36] and 3.46 mm [*SD*: 0.36]; (mean of Δ: 0.25mm (*SD*: 0.35); (95% CI: 0.29–0.21); (p = .036) for the right and left side, respectively).

The mean measured mouth opening was 4.63 mm (*SD*: 0.58). In the navigation group, no statistically significant correlations were found between the mouth opening values and any parameter deviations. A statistically significant correlation was found between the angular deviations and mouth opening for the implants placed by the freehand technique (r_s = .373, p = .042).

No statistically significant models were fitted that could be regarded as an evidence of a learning curve. Mean linear deviation values measured on the consecutive cases were plotted on a graph, and no apparent trend showing a reduction in the deviations was observed (Figure 4).

4 | DISCUSSION

Reliability regarding the transfer of the virtually planned implants to the posterior maxilla via the conventional freehand surgery or the guidance of a micron tracker-based dynamic navigation device was analysed in this split-mouth randomized trial. Freehand execution of the interventions by an experienced surgeon yielded acceptable maximum deviation values (<9mm linear and < 20.42° angular) and the assistance by the dynamic navigation device provided an additional approximate 0.7mm linear and 5° angular accuracy. Standardization of various variables such as the implant dimensions and area of the application might have yielded such small deviation values. However, higher discrepancies would be expected with the use of longer implants in other regions of the mouth (Ozan, Orhan, & Turkyilmaz, 2011). The flip of a coin, which was preferred to avoid excessive dropouts (relating due to unforeseeable technical or surgical events), is a potential limitation in the present methodology. It is not desirable in the modern research practices and may have introduced additional unrecognized covariates. Also, the present sample size calculation based on the implant fixtures may yield higher requirements if calculated on the patient level (Lesaffre et al., 2009). Therefore, the results of this study should be evaluated with caution.

While the accuracy between the planned and placed implants inserted by the static surgical stents was extensively studied

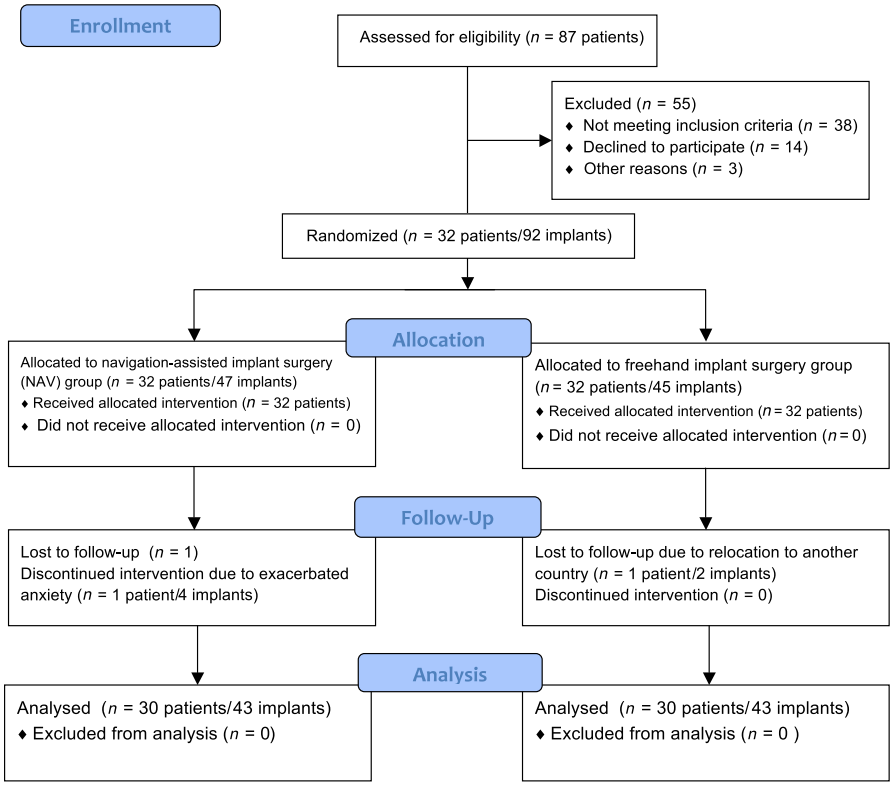

FIGURE 2 Study flow diagram

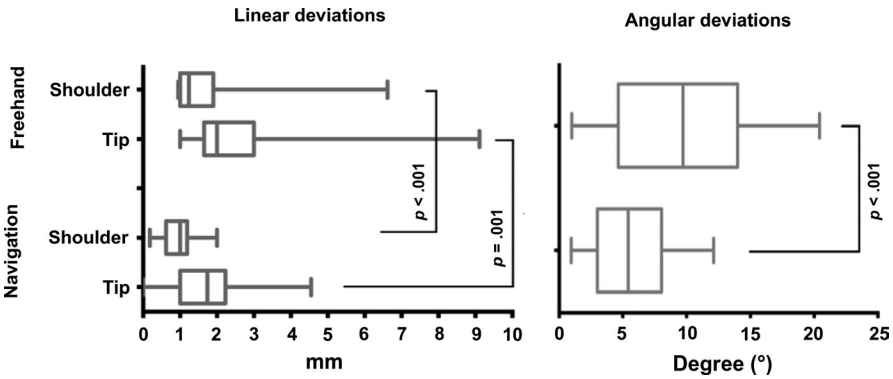

FIGURE 3 Box plots showing the median, quartile, and range values for the linear and angular deviations in the shoulder and tip of implants

(Tahmaseb, Wismeijer, Coucke, & Derksen, 2014; Zhou, Liu, Song, Kuo, & Shafer, 2018), such studies are limited for the dynamic navigation system. Most of these studies are confined to arbitrary case series without a valid control (Guo et al., 2018). Proven benefits of the guided implant surgery prompted its spread in clinics via the static guides possibly as a result of many emerging open-source planning software and low-cost 3D printing opportunities that facilitate inexpensive manufacturing of guides. While the comparison of the accuracy studies is prone to errors due to many technical factors, it was concluded that a respective linear deviation of 1.12 (range: 0.6–4.5) and 1.53 (range: 0.81–7.1) mm at the implant shoulder and tip could be expected (Tahmaseb et al., 2014). Similar results were also reported by a systematic review in which the clinical studies yielded an approximate 30% higher deviation than in vitro analyses (Jung et al., 2009). In a recent meta-analysis, a 4.1-degree mean angular deviation value was calculated from of the 1513 implants meeting the inclusion criteria (Zhou et al., 2018). Statistically significant angular and linear reduction with the use of screw-fixated single-type static guides ($p < .001$) was also reported. Hence, given the consolidation of results on the accuracy of static guides, such an arm was not considered in this study. It should also be remembered that the closed, restrictive structure of the static guides might hinder early detection of extreme deviations that correspond to the maximum reported deviation values. Such an error risk is much less likely with the use of a navigation device because it allows full visibility of the surgical area and the final implant position.

It is once again observed that studies commenced on laboratory conditions produced higher accuracy rates than clinical studies. Gunkel and co-workers utilized this technology in its early versions. They reported 1- to 2-mm deviations after surpassing an initial learning curve (Gunkel, Freysinger, & Thumfart, 2000). Wanschitz and co-workers employed a similar setup and achieved an accuracy rate of 0.96-mm (*SD*: 0.72) linear deviation (range: 0 to 3.5 mm) between the planned and placed implants tested on dry human cadavers

TABLE 1 Deviations between the planned and placed implants in freehand and navigation groups

		Freehand *n* = 43		Navigation *n* = 43	
		Implant shoulder	Implant tip	Implant shoulder	Implant tip
Linear deviations (mm)	Mean (*SD*)	1.70 (0.13)	2.51 (0.21)	1.01 (0.07)	1.83 (0.12)
	Min- max	0.95–6.62	1.18–9.11	0.41–2.00	0.11–4.55
	95% CI	1.46–1.99	2.13–2.95	0.87–1.18	1.60–2.10
	Mean of Δ at the shoulder: 0.72mm (*SD*: 0.26); (95% CI: 0.39–1.02) Mean of Δ at tip: 0.69mm (*SD*: 0.36); (95% CI: 0.19–1.19)				
Angular deviations (°)	Mean (*SD*)	10.04 (0.83)		5.59 (0.39)	
	Min–max	2.19–20.42		2.06–10.18	
	95% CI	8.51–11.85		4.87–6.42	
	Mean of Δ between the angles: 5.33° (*SD*: 1.63); (95% CI: 7.17–3.48)				

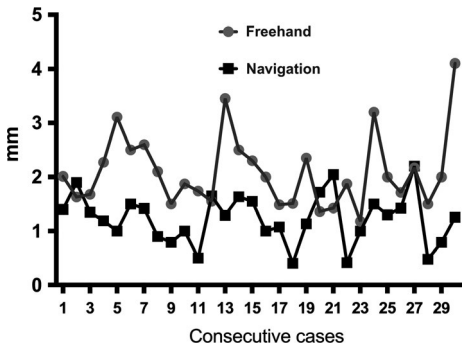

FIGURE 4 Mean linear deviation plots in consecutive volunteers

(Wanschitz et al., 2002). Somogyi-Ganns, Holmes and Jokstad (2015) prepared a clinical setup represented by a typodont in a manikin and tested three popular static guidance systems (Simplant (Materialise Dental, Leuven, Belgium); Straumann Guided Surgery, (Institute Straumann AG, Basel, Switzerland); NobelClinician, (Nobel Biocare AG, Zurich, Switzerland)) against an early prototype of the navigation system used in this study. All systems, including laboratory-made acrylic guides, provided an acceptable deviation rate (<2 mm linear and 5° angular), while the navigation system provided a higher accuracy (1.14 and 1.71 mm linear and 2.99° angular). The differences were statistically significant. Given the similarity to the present study's results, the setup of Somogyi-Ganns et al. (2015) could be regarded highly realistic for translational research purposes.

Considering the additional costs and labour, the benefits of the guided implant surgery, especially in case of a navigation device, have been debated against the conventional freehand technique. Aside from other benefits, such as reduced trauma and surgery duration, the positional accuracy of implants placed by the freehand method was lower in all reports. In a clinical trial including static guidance systems, Vercruyssen et al. (2014) measured 2.77 (*SD*: 1.54) and 2.91 (1.52) mm linear and 9.92 (*SD*: 6.01) ° angular deviations of implants planned and placed by "mental navigation," and the differences between the computer-guidance groups were statistically significant (Vercruyssen et al., 2014). Nickenig and co-workers (Nickenig, Wichmann, Hamel, Schlegel, & Eitner, 2010) measured the deviations of implants placed to the replica plaster models of 10 patients who were previously received actual implants. They reported a significantly higher linear (3.5 mm [*SD*: 5.4] in the shoulder and 2.5 mm [*SD*: 1.8] in the tip) and angular deviation rate (10.9° [*SD*: 4.5]). These results correspond to the deviation values measured in this study. Taken together with the previous findings, it can be concluded that freehand dental implant placement will result with a lower accuracy compared with computer-aided methods. This can be particularly important when implant instillation is planned in the vicinity of critical anatomy.

Many of the previous reports are based on arbitrary collection of cases without any priori sample size calculation; therefore, a direct comparison of the present results may not be feasible. In 100 consecutive cases, Block and co-workers (Block, Emery, Lank, & Ryan, 2017) employed a navigation device based on infra-red beam light triangulation technology and reported a mean 0.87 (*SD*: 0.42) and 1.56 (*SD*: 0.69) mm linear deviation at the implant shoulder and tip, respectively. Freehand insertion of implants yielded with a significant increase of discrepancies with a mean 1.15 (*SD*: 0.59) and 2.51 (*SD*: 0.69) mm linear deviation at the implant shoulder and tip, respectively. Corresponding angular deviation (9.1 (*SD*: 4.99°) differences were also statistically significant ($p < .001$), and the authors concluded that the feasibility of dynamic navigation was favourable in partially edentulous cases. In a retrospective analysis (Stefanelli, DeGroot, Lipton, & Mandelaris, 2019) where the identical micron tracker device was used for the treatment of 89 consecutive cases, measured mean linear deviations were less than 1 mm. Hence, almost perfect angular deviation values (mean: 1.65°) were also reported for the same group of 99 implants. Measured deviation values in this clinical trial were higher than both of these studies (>1 mm mean linear and > 5° angular). However, it should be noted that due to variant execution and use of imaging, matching and measurement techniques (i.e. mesh, surface extraction and vector registration), and the results would be skewed. It can be concluded that irrespective of the employed navigation technology, these sophisticated devices provide better accuracy than the freehand method, and no

critical collision was reported, verifying the safety of these devices. It should also be noted that the deviations markedly increased at the tip of the implant. A similar outcome was noted in previous studies employing static guides (Arisan, Karabuda, Mumcu, et al., 2013; Arisan et al., 2010) and similar navigation devices (Herklotz et al., 2017). It was previously reported that a shift during the insertion of the implant was notable, especially in low-density bone areas (Ozan et al., 2011). This information can be particularly relevant to this trial given that the region of application was exclusively restricted to the posterior maxilla, and the implant bodies may have shifted towards least resistance (spongiosa) during screwing. Hence, it would be reasonable to assume that side of application and the amount of mouth opening would impact the virtual clarity of the technical components (i.e. tracking cameras, geometric patterns and reflections) and the resulting deviations. While some studies mentioned the effect of such interferences, no significant relations were found in this study. Proper execution of the technical equipment and components potentially provided this result.

The graphical representation of the rate of learning how to place implants with better accuracy over time or repeated experiences can be defined as the learning curve (Kassite, Bejan-Angoulvant, Lardy, & Binet, 2019). Such a curve was implied by the aforementioned two previous studies (Block et al., 2017; Stefanelli et al., 2019), revealing a trend towards a lower deviation rate after 15 to 25 cases. In contrast, no statistically significant learning curve was found in this study when incorporating all variables in a single analysis model. The accuracy trend fluctuates thought the consecutive implants or patients, and this fluctuation can be attributed to the randomization process and/or the relatively small group of subjects. Albeit, the validity of the methods in the detection of a learning curve other than the current analysis is speculative and open to debate due to violation of the statistical assumptions and sectioning of the data sets (Ramsay et al., 2001). It is the authors' opinion that the application of osteotomy via the aid of a dynamic navigation system differs from the conventional technique, and prior training on phantom models and consequent cases will establish a clinician's confidence in time that can be defined as "learning." Without sufficient hands-on and clinical training, clinicians would feel uncomfortable and insecure. Angulation and drill depth are traced on the computer screen, which forces the clinician to look at a region other than the patient's jaw and osteotomy site, which is unusual for a dental surgeon. We think this issue is the biggest drawback of the current systems and industry should address this important issue.

5 | CONCLUSIONS

Randomization technique and the sample size calculation employing the implant rather than the patient as a unit of analysis were the limitations of this study.

Even with the use of sophisticated equipment, deviation-free placement of implants in a consistent manner was not possible, and mean linear deviations were greater than 1 mm. Compared with the freehand technique, approximate 0.7mm and 5° reductions for in linear and angular deviations, respectively, were achieved by means of the micron tracker navigation device. The described dynamic navigation technique can be used for the transfer of pre-operative virtual implant planning to the patient's jaw with a higher accuracy than the freehand method. Attempts should be made to facilitate familiarization of the osteotomy practices in the "computer screen-displayed" navigation systems in oral implantology.

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AUTHOR CONTRIBUTION

CAA contributed in the design of the study, completed the legal allowance procedures, assisted in the clinical setup and execution of the procedures, collected the data and assisted in the preparation and submission of the article.VA designed the study, executed the surgeries, collected data, analysed the results with the statistician and written and revised the final manuscript.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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