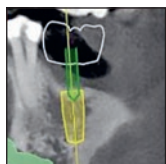# Accuracy of a Novel Trace-Registration Method for Dynamic Navigation Surgery

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A technology called Trace Registration (TR) has been introduced to allow dynamic navigation of implant placement without the need for a thermoplastic stent. This study was undertaken in order to validate the accuracy of the TR protocol for dynamically guided implant surgery. A retrospective, observational, in vivo study was performed using dynamic navigation via the TR protocol. The preoperative cone beam computed tomography (CBCT) plan was superimposed and registered (aligned) with the postoperative CBCT scan to assess accuracy parameters. A total of 136 implants were placed in 59 partially edentulous arches. Mean deviation between the planned and actual position for all implants was 0.67 mm at the coronal level (entry point), 0.9 mm at the apical level, and 0.55 mm in depth, with an angle discrepancy of 2.50 degrees. Tracing 5 to 6 teeth tended to improve accuracy results compared to tracing 3 to 4 teeth. TR is as accurate as traditional registration and statically guided methods for implant surgery. Int J Periodontics Restorative Dent 2020;40:427–435. doi: 10.11607/prd.4420

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Computer-aided implantology (CAI) has been globally embraced because it offers a number of advantages over freehand surgery. Importantly, CAI allows for more accurate and minimally invasive surgery, reduces the risk of damage to nearby structures, and allows improved restorative efficiency by predictably translating prosthetic planning into surgical execution.[1–6] Two CAI methods are currently in use: static CAI (SCAI), which requires the design, fabrication, and use of a physical guide with drilling sleeves[7,8]; and dynamic CAI (DCAI), which uses a GPS-like system to provide visual feedback to the implant surgeon.[9–13] While the two approaches currently appear to provide comparable in vivo placement accuracy,[1–3,14–18] DCAI provides a simpler, faster, and more flexible workflow with an easy and reliable accuracy check to reduce large placement errors.[9–13]

The traditional DCAI workflow, available in all commercially available DCAI systems, consists of four steps: *(1)* Preparation of a thermoplastic stent (or clip), required for fixation of a radiopaque fiducial marker on the arch (mandible or maxilla) to be treated; *(2)* patient cone beam computed tomography (CBCT) scanning with the stent fixed in the mouth; *(3)* prosthetically directed implant-surgery treatment planning; and *(4)* guided implant

placement with the stent remounted on the arch, holding a tag with optical markers that provide a coordinate reference frame for the arch during surgery.

In this workflow, it is essential to have one or more fiducial markers (rigid objects with a known shape) present and clearly visible in the patient's CBCT scan. The precise location of the fiducial marker in the CBCT scan is required for the registration of the scan and is used as reference when preparing the surgical plan. This fiducial marker is affixed to the patient's arch using a thermoplastic stent, which is typically fabricated directly on the patient's residual dentition. To enable accurate registration, the stent must be secured in the exact same location and orientation relative to the arch's bone during the acquisition of the CBCT scan, the entire osteotomy site preparation, and insertion of the implants. A loose or inconsistently positioned stent will result in an irreversible or erratic guidance error, compromising the accuracy of the navigated surgery, often requiring that guidance to be abandoned.

Other drawbacks of the use of a stent/fiducial approach include the need for an extra CBCT scan (more time, radiation, and perhaps patient travel); extra stent-preparation time (including heating with boiled water and slow cooling of the thermoplastic material); the need for personnel to acquire stent-preparation skills; the need to ensure proper visibility of the fiducial body (or bodies) in the scan; the interference of the stent in scanning the arches in occlusion;

and the potential interference of the stent when positioning a handpiece near the drilling site.

To overcome the aforementioned drawbacks, a technology called Trace Registration (TR) was recently introduced (Navident, ClaroNav) and promoted commercially as TaP ("Trace and Place") for its Navident 2 system. Instead of a radiographic fiducial marker, TR utilizes structures that are naturally visible in the scan, such as teeth, abutments, or certain types of restorations. Unlike the fiducial markers, which have a fixed and known shape, the shape of these structures needs to be sensed by the navigation system prior to surgery, utilizing a "surface contact scan" approach. A ball-tip stylus, called a Tracer, is used to trace between 3 to 6 short paths over regions within the arch. A sequence of one hundred or more ball-tip positions is collected during each trace and aligned directly with the volumetric CBCT image data (no explicit surface segmentation is needed). This provides registration mapping between the CBCT and the physical patient's arch.

Similar types of surface-based registration are available and have been used in other types of clinical, surgical procedures, such as endoscopic sinus surgery, using the patient's face shape to register their head to their respective clinical CBCT. However, TR was not available until the release of Navident 2.0 in 2018. This paper is, to the best of the authors' knowledge, the first report on the in vivo use of this technology in dynamic-navigation implant surgery.

The aim of this study was to evaluate the in vivo accuracy of using TR for implant placement and to compare it to the in vivo accuracy obtained using the same system with the stent/fiducial method used in a previously published study. In addition, the impact of the number of registration teeth traced on outcome accuracy was evaluated.

Materials and Methods

A retrospective, in vivo case series was performed using a dynamic navigation system (Navident 2.0, ClaroNav).

The CBCT studies used in planning and during guidance were provided by patients who had been referred for implant placement from other facilities. The variability of the scans was acceptable because the navigation software is not linked to any specific CBCT machine. This minimized the amount of radiation exposure to the patient.

Postoperative scans were taken using a proprietary low-dose imaging-technology scan (5 × 5 cm; OP 3D Pro, Kavo) to assess the correct position and angulation of implants and the overall quality of the implant placement procedure. The use of a postoperative CBCT scan for this study 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). Implants included in the analysis were placed

from January to December of 2018 using the TaP protocol for dynamic navigation surgery. Patients with general contraindications to 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 number of residual teeth traced for the registration was recorded as either three to four or five to six. All implants were placed by a single surgeon (L.V.S.).

Fig 1 *Implant planning using a digital wax-up as reference for a prosthetic-driven implantation.*

The TR Protocol

The TR protocol consists of three steps: *(1)* Plan: creation of the surgical plan on the basis of the volumetric DICOM (Digital Imaging Communication in Medicine) data acquired from a CBCT scan (typically, the digital work flow is completed through the planning software by merging an intraoral surface scan of the patient, which includes a virtual or digital diagnostic wax up of the prosthetically directed, optimal final tooth position); *(2)* Trace: registration based on tracing structures marked on the CBCT; and *(3)* Place: navigated implant placement according to the plan.

Plan
CBCT images in DICOM format were imported into the Navident software. Stereolithographic images of the residual teeth were made w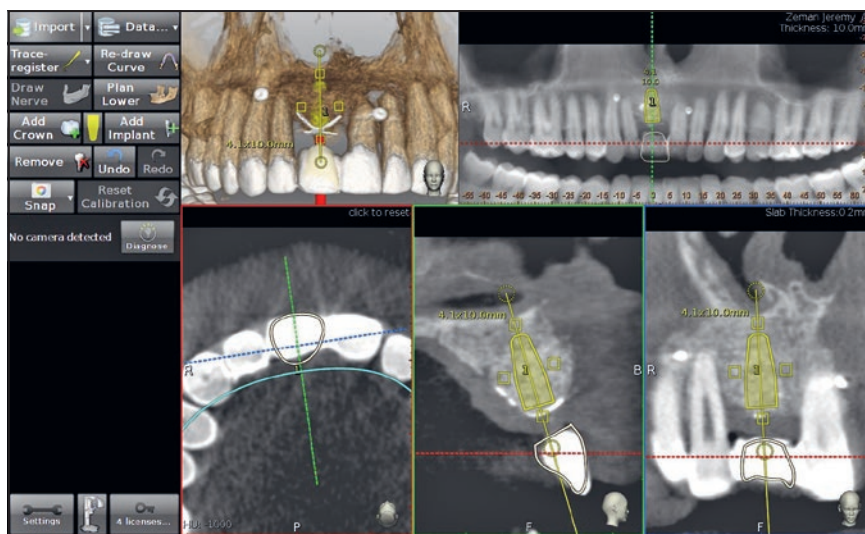ith an intraoral surface scanner (iTero Element 2, Align Technology), and a digital wax-up of the missing teeth was completed. This was imported into the Navident software and overlapped semi-automatically to the residual teeth by using the mesh-to-image registration tool provided. Implant placement was then prosthetically planned utilizing the digital wax-up of the missing tooth (Fig 1). As part of the planning, the surgeon marked 3 to 6 landmarks on hard tissue structures, typically teeth, to be used as the starting points for tracing on the patient's teeth.

Trace
For the system's camera to track the patient's arch, an optical tracking tag needs to be affixed to the arch in which surgery is being performed. This requires either a JawTracker (a combination of the optical tag and a bendable metal wire) connected to 1 to 2 teeth in the residual dentition with a light-cured composite resin (Fig 2); or, for the maxilla, a HeadTracker that is installed directly on the patient's head to track the maxilla (Fig 3).

Tracing can then be performed, starting at the landmark locations. During tracing, the surgeon slides the tracer's ball tip over the surface of a tooth until a 15-cm path has been traced (Fig 4). The system audibly indicates the tracing progress, enabling the surgeons to look directly at the structure being traced.

After tracing all selected teeth, the software automatically performs the registration process. The sampled trace points are aligned with strong edges in the CBCT image. No prior segmentation of the image is needed to extract the

Fig 2 *JawTracker used in the mandible for the dynamic navigation (Navident 2).*

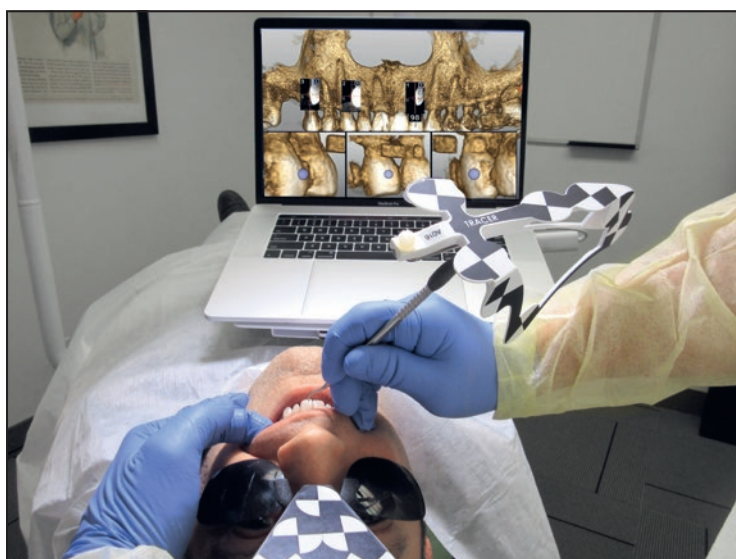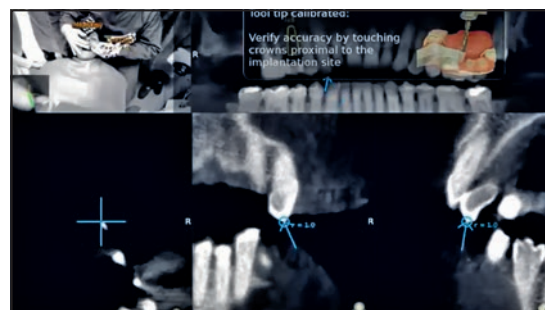Fig 3 *HeadTracker used in the maxilla for dynamic navigation (Navident 2).*

Fig 4 (left) *Tracing progress.*

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

surface registration. The complete registration process typically takes 1 to 2 minutes, and the quality of the TR can be evaluated instantly in the software.

The surgeon can then clinically verify the registration accuracy by touching the tracer's ball tip on the patient's teeth at several aspects and comparing the actual physical location of the tracer tip with its representation on the system's screen. If the registration accuracy is unsatisfactory, the tracing step can be immediately repeated (Fig 5).

Fig 6 (right) *Accuracy check performed by touching a tooth cuspid, showing the accuracy of the dynamic navigation workflow.*

Fig 7 (below left) *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.*

Fig 8 (below right) *Several views appear on the screen during surgery: (1) tracker video stream, (2) panoramic view, (3) mesiodistal section view, (4) buccolingual section view, (5) depth indicator, and (6) target view.*
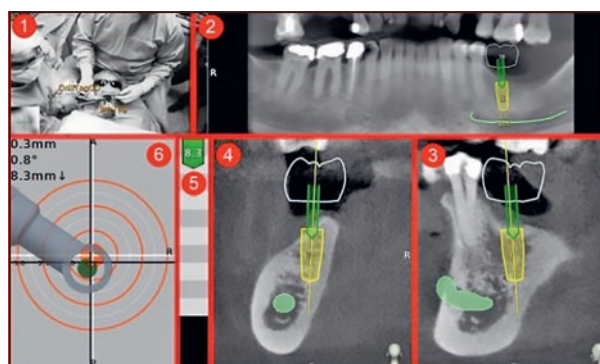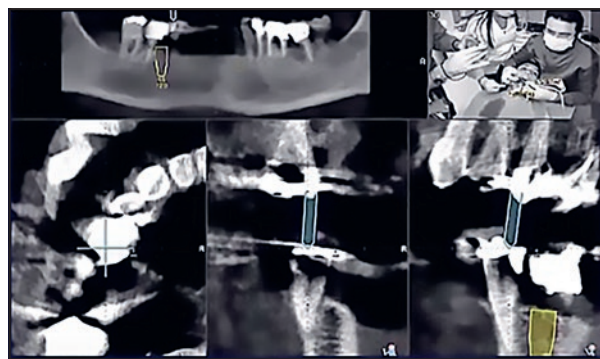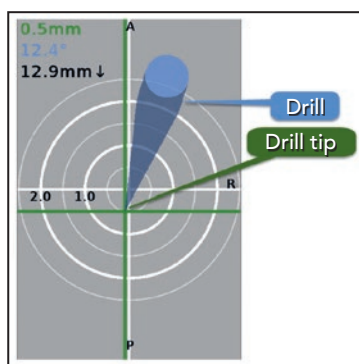
Place

The surgical drill's axis and tip are calibrated, and a second verification of the accuracy is carried out in the same way as with the tracer (Fig 6). Once the accuracies of the drill axis and tip are verified, the navigated implant placement can be carried out following the target view that allows the clinician to observe, in real time, the depth, angulation, and entry point of the planned osteotomy as related to the plan. The coronal and sagittal views shown on the screen enable the clinician to follow the position of the drill during the osteotomy (Figs 7 and 8). As with all of the dynamic navigation systems, the surgeon must not bump or distort the position of the patient-tracking array during surgery, as this has the potential to introduce error into the navigation.

Placement Accuracy Evaluation

Following each surgery, the patient underwent a postoperative CBCT scan. Using an accuracy evaluation application (EvaluNav) provided through the Navident navigation system, the preoperative surgical plan and the postoperative CBCT are superimposed. The registration is done directly between the two volumetric images, and the software provides various visualization tools to confirm that the two images are precisely aligned and to improve the accuracy if it is less than ideal. The accuracy evaluations were completed off-site by an examiner not involved in the surgery (F.D.A.).

Once the user is satisfied with the volumetric registration, the software automatically fits a model of the implant to its appearance in the postoperative image and computes the entry point deviation and angle discrepancy between the planned and actual implant locations (Figs 9 and 10). The accuracy of the entry-point deviation and angle-discrepancy measurements were validated on models by the manufacturer.

The data collected for all implants reported here were loaded into Microsoft Excel spreadsheets, and Excel's built-in functions were used to compute the statistical values reported (average, standard deviation [SD], 95th percentile, and *t* test).

Fig 9 *Overlapping between the pre- and post-CBCT.*

Fig 10 *Evalunav software determines implant accuracy of the TR (Navident 2) protocol.*
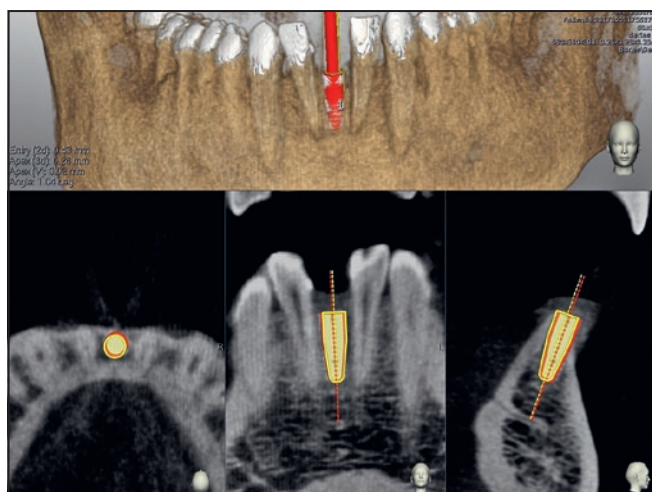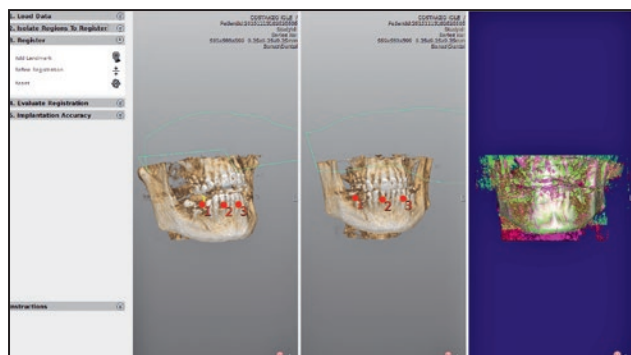
Results

Between January and December of 2018, a total of 136 implants were placed in 59 partially edentulous patients with guidance using the TR protocol. Thirty-nine cases involved the maxilla (75 implants), and 36 cases involved the mandible (61 implants). Registration involved tracing 3 to 4 teeth for 69 implants and tracing 5 to 6 teeth for 67 implants.

Data on the number of patients and treatment locations are reported in Appendix Table 1 (All Appendix Tables can be found in the online version of this article at www.quintpub.com). The number of patients and implants where surgery was performed following tracing of three to four vs five to six teeth is also shown in Appendix Table 1.

The mean deviation between the planned and actual position for all implants was 0.67 mm at the entry point, 0.9 mm at the apex, and 0.55 mm in depth, with an angular deviation of 2.50 degrees (Appendix Table 2).

Data organized by the arch being treated are presented in Appendix Table 3. There was a small but significant difference in apical accuracy, favoring the mandibular implants. There were no other significant differences between the results of the maxillary and mandibular implants ($P > .05$).

Differences between mean *t* test data from the maxillary and mandibular locations are shown presented in Appendix Table 4. Appendix Table 5 compares mean *t* test data between implants inserted by tracing three to four teeth vs five to six teeth.

The 95th percentile values were also computed for the present TR data and were compared with data previously published, obtained using the thermoplastic stent and fiduciary marker (Appendix Table 5) and the same navigation system. The surgeries that produced the "historic control" data were completed by the same surgeon and in the same facilities with the only significant difference in protocol being the means by which the patient registration occurred (TR vs thermoplastic stent).[11]

Data organized by the number of teeth used for TR are presented in Appendix Table 6. Tracing five to six teeth for registration significantly improved all accuracy outcomes compared to tracing only three to four teeth.

Figure 11 demonstrates the mean entry point deviation of all implants when three to four teeth were traced for registration compared to tracing five to six teeth. Figure 12 demonstrates the mean angle discrepancies of all implants when three to four teeth were traced for registration compared to five to six traced teeth. In both analyses, accuracy was improved by registering more tooth surfaces compared to fewer.

Discussion

TR technology provides a completely digital workflow by eliminating reliance on the prefabrication of analog appliances. It removes the
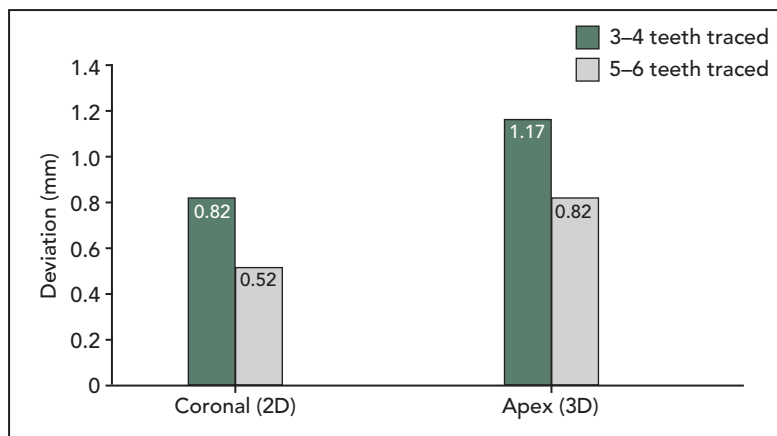
Fig 11 *Mean coronal (entry point) deviation of all implants when three to four teeth were traced for registration as compared to five to six teeth traced.*
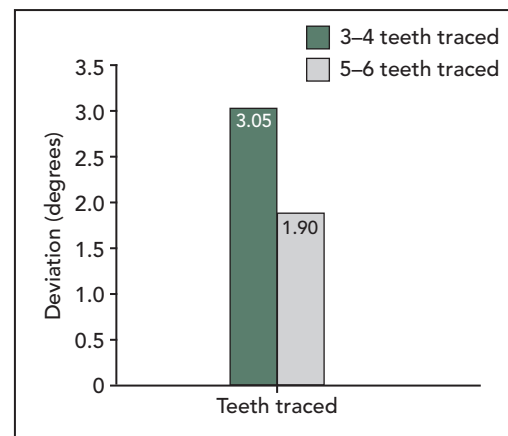
Fig 12 *Mean angle discrepancies of all implants when three to four teeth were traced for registration as compared to five to six teeth traced.*

time-consuming and technique-sensitive step of fabricating a custom stent prior to the procedure, minimizes the need to re-scan patients to obtain a CBCT containing a fiducial marker, and provides the surgeon with improved access to the mandibular and maxillary operation sites (surgery not performed with thermoplastic stent in place). These factors make using navigation technology for implant placement more efficient and more widely applicable. These workflow benefits are, however, rather meaningless unless the technology is at least as accurate as more traditional guided surgery. Thus, the purpose of this study was to evaluate the accuracy of implant placement using TR technology for navigated surgery.

In a systematic review of the literature on statically guided implant surgery in partially edentulous arches, Tahmaseb et al found the average error of implant position to be 0.9 mm at the entry point, 1.2 mm at the apex, and roughly 3.3 degrees off axis.[1,19] While the literature is re-

plete with data on the accuracy of static CAI, there are relatively few studies evaluating dynamic guided surgery.

Early research on first-generation navigation systems seemed to show similar clinical outcomes, with accuracy reported between 1 and 2 mm depending on the study.[20–24] As the technology advanced, the accuracy trends improved. Somogyi-Ganss et al used an early prototype of a second-generation dynamic navigation system for an in vitro study on accuracy[25]: Eighty osteotomies were completed with reported mean deviations of 1.14 mm for entry-point deviation, 1.71 mm for apex deviation, and 2.99 degrees for the axis.[25] Other in vitro research, completed by Jorba-García et al as well as Chen et al, demonstrated similar results for dynamically guided implant placement.[26,27]

An in vivo study reported by Block et al evaluated the accuracy of implant placement using the X-Guide dynamic navigation system (X-Nav Technologies) in 100

partially edentulous patients.[13] The reported mean ± SD deviations for implants were 0.87 ± 0.42 mm at the entry point (lateral/two-dimensional [2D]), 1.56 ± 0.69 mm at the apex (three-dimensional) and 3.62 ± 2.73 degrees for the axis. Nonguided entry-point deviations, apex deviations, and angle discrepancies had corresponding values (mean ± SD) of 1.15 ± 0.59 mm, 2.51 ± 0.86 mm, and 7.69 ± 4.92 degrees. No statistically significant differences between individual surgeons were observed in the navigated placement.

Additional in-vivo research, using traditional fiduciary markers and a thermoplastic stent for registration in dynamic navigation surgery, was completed by Stefanelli et al[11] using the Navident dynamic navigation system (ClaroNav). This study evaluated the accuracy of 231 implants in 89 arches. The reported deviations for implants were 0.71 mm at the entry point (lateral/2D), 1 mm at the apex, and 2.26 degrees off the planned axis.

Taken together, current guided systems (whether statically or dynamically guided) consistently show deviation at the point of entry to be slightly less than 1.0 mm, apical deviations are more often 1 to 1.5 mm, and angle deviations tend to fall between 2 and 4 degrees.

In the present study, the mean deviations between the planned and actual implant positions were found to be 0.67 mm (lateral/2D) at the entry point, 0.9 mm at the apex (lateral/2D), and 0.55 mm at the apex (vertical), with an angular deviation of 2.50 degrees. These results are consistent with the results reported in the literature regarding the use of CAI (static guides and dynamic navigation systems). The present data show that TR is at least as accurate as traditional registration methods involving a fiduciary marker and thermoplastic stent in dynamic navigation surgery based on published data by the same surgeon, in the same facility, using the same navigation surgery system.

Importantly for clinical application, the 95th percentile deviations were dramatically lower when using trace registration compared to a thermoplastic stent, especially when more than four teeth were used for trace registration. The fact that there was less deviation in "outlier" cases has important implications for patient safety and surgical success. This may be attributable to the fact that trace registration allows for retracing and re-registering a patient following an unsatisfactory accuracy check. This real-time recalibration is not possible when a static-based guide is used for patient registration, and the surgeon may be left with the choice of accepting partial inaccuracy or completing the surgery with a freehand approach.

Some limitations of TR were discovered during this study. The most significant one is that the surface being traced must be easily distinguishable in the CT images. Some porcelain-fused-to-metal crowns cannot accurately be used for tracing due to the very low radiographic density of the porcelain layer next to the very high density of the metal coping underneath. Full-metal, zirconium, or full-porcelain crowns may, however, be used for tracing. Also, periodontally compromised or excessively mobile teeth cannot be used, as they lack the positional stability required for an accurate registration. Finally, surfaces of resin or composite restorations often cannot be distinguished when in contact with soft tissue or saliva.

In this study, unstandardized CBCT images (from different sites with different CBCT units) were utilized in order to minimize radiation exposure to the patients. While all of the data were transferred into the Navident software for planning and for evaluation, it would be impossible to say exactly what impact, if any, differing voxel sizes or image quality may have had on the data.

The use of TR in the fully edentulous arch is currently experimental and may require the presence or addition of fixed reference points, such as bone tacks or screws, to ensure sufficient accuracy. Further research efforts are needed to ensure the efficacy of this treatment modality.

It is important to note that, unlike SCAI (surgical guides) and stent/fiducial-based DCAI technologies (which have been available commercially for well over a decade), TR is a recent addition to the implantology armamentarium. Thus, some of its limitations may be overcome as the technology continues to improve and advance. Also, because its accuracy is not limited by the repeated seating/unseating of a semi-rigid plastic stent or by the fit between a drill and a sleeve, it is not unreasonable to assume it could eventually achieve better accuracy than these analog modalities. Continued studies will be needed in order to evaluate the potential for improved accuracy as the technology continues to advance.

Conclusions

The accuracy of TR technology for dynamically guided implant placement was evaluated in vivo. The average deviations between the planned and final implant locations (0.67 mm at the entry point, 0.9 mm at the apex, and an angular deviation of 2.50 degrees) compare favorably with published data on both statically and dynamically guided surgery using a thermoplastic stent. Additionally, there was found to be less deviation of the "outlier" (95th percentile deviation) implants when using TR technology compared to a thermoplastic stent. Tracing five to six teeth for patient registration was found to be significantly more accurate than tracing three to four teeth.

While the technology is relatively new, TR provides a completely

digital workflow for implant placement. It reduces the need for additional patient radiation (an additional CBCT), removes the intraoffice time for stent fabrication, and allows for real-time recalibration if any inaccuracy is detected. TR registration technology is an important step towards a simplified, streamlined, and predictable digital workflow for dynamic navigation surgery. Based on the present accuracy-evaluation data, TR registration is at least as accurate as traditional registration methods involving a fiducial marker and thermoplastic stent in dynamic navigation surgery.

Acknowledgments

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Appendix

Appendix Table 1 Patient and Treatment Characteristics

	Patients, n	Implants, n
Total	59	136
Treatment location		
Maxilla	39	75
Mandible	36	61
Teeth traced, n		
3–4	34	69
5–6	42	67

Appendix Table 2 Mean Deviation for All Implants

Deviation of inserted implants (N = 136)	Mean	Minimum	Maximum	SD
Coronal, mm	0.67	0.11	1.45	0.29
Apical (3D), mm	0.99	0.12	2.01	0.33
Apical (depth), mm	0.55	0.01	1.5	0.25
Angular, degrees	2.5	0.35	5.81	1.04

SD = standard deviation; 3D = three-dimensional.

Appendix Table 3 Mean Implant Deviations Based on Implant Location

Deviation	Maxilla (SD)	Mandible (SD)	Difference	P
Coronal, mm	0.7 (0.28)	0.64 (0.30)	0.06	.21
Apical (3D), mm	1.05 (0.34)	0.92 (0.31)	0.13	.02
Apical (depth), mm	0.57 (0.27)	0.52 (0.24)	0.06	.14
Angular, degrees	2.8 (1.16)	2.14 (0.74)	0.66	.01

SD = standard deviation; 3D = three-dimensional.

Appendix Table 4 Mean Implant Deviations Based on the Number of Teeth Traced for TR

Deviation	3–4 teeth traced (SD)	5–6 teeth traced (SD)	Difference	P
Coronal, mm	0.82 (0.24)	0.52 (0.27)	0.30	.05
Apical (3D), mm	1.17 (0.29)	0.82 (0.28)	0.35	.05
Apical (depth), mm	0.67 (0.22)	0.43 (0.24)	0.25	.05
Angular, degrees	3.05 (0.93)	1.90 (0.74)	1.16	.05

TR = trace registration; SD = standard deviation; 3D = three-dimensional.

Appendix Table 5 95th Percentile Values Computed and Compared with Corresponding Measurements Using the Stent Approach[11]

	Implants, n	Mean deviation			95th percentile deviation		
		Coronal (2D), mm	Apex (3D), mm	Angle, degrees	Coronal (2D), mm	Apex (3D), mm	Angle, degrees
TR approach							
Total	136	0.67	1.00	2.50	1.19	1.44	4.16
Mandible	61	0.64	0.92	2.14	1.2	1.33	3.34
Maxilla	75	0.70	1.06	2.80	1.15	1.49	4.49
3–4 teeth traced	69	0.82	1.17	3.05	1.26	1.54	4.39
5–6 teeth traced	67	0.52	0.82	1.90	1.00	1.30	3.09
Stent approach, total[11]	231	0.71	1.00	2.26	1.48	1.88	5.53
P (t test), %							
Manidble vs Maxilla		21.2	2.0	14.8			
3–4 vs 5–6 teeth		.0	.0	.0			

Measurments from the stent approach were obtained by the same authors, with the same surgeon using the same navigation system for the stent approach.