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Accuracy of complete-arch digital implant impression with intraoral optical scanning and stereophotogrammetry: An in vivo prospective comparative study

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Abstract

Objectives: To assess accuracy of intraoral optical scanning (IOS) and stereophotogrammetry (SPG), complete-arch digital implant impressions in vivo.

Materials and Methods: Consecutive patients needing implant-supported screw-retained zirconia complete-arch fixed-dental prostheses (ISZ-FDP) were recruited. For each patient, three impressions were taken: IOS, SPG (tests), and open-tray plaster (reference). Linear (ΔX, ΔY, and ΔZ), three-dimensional (ΔEUC), and angular deviations (ΔANGLE) were evaluated and stratified according to scanning technology for each implant. Potential effects of impression device (IOS and SPG), arch (maxilla and mandible), and implant number (4 and 6) were evaluated through multivariable analysis. Significance level was set at .05.

Results: A total of 11 complete arches (5 maxillae, 6 mandibles) in 11 patients were rehabilitated with ISZ-FDPs supported by 4 ($n=8$) and 6 implants ($n=3$). A total of 50 implants and 100 implant positions were captured by two investigated devices and compared to respective reference (mean ΔEUC IOS 137.2, SPG 87.6 µm; mean ΔANGLE 0.79, 0.38°). Differences between measurements (SPG-IOS) were computed for each implant, with negative values indicating better SPG accuracy. Significant mean ΔEUC difference of −49.60 µm ($p=.0143$; SD 138.15) and mean ΔANGLE difference of −0.40° ($p<.0001$; SD 0.65) were observed in favor of SPG. Multivariable analysis showed significant effect on ΔEUC ($p=.0162$) and ΔANGLE ($p=.0001$) only for impression devices, with SPG performing better.

Conclusions: SPG experienced significantly higher linear and angular accuracy. No effect of type of arch or implant number was detected. Higher extreme deviations were experienced for IOS. SPG can be feasible for complete-arch digital impressions with caution, and rigid prototype try-in is recommended before screw-retained prosthesis manufacturing.

KEYWORDS
complete arch, dental implant, digital impression, intraoral scanner, stereophotogrammetry

1 | INTRODUCTION

Screw-retained complete-arch fixed-dental prostheses (FDPs) need accurate matching between implants and frameworks to achieve long-term successful outcomes (Sanda et al., 2021). The target is to deliver an FDP that properly fits the prosthetic platforms without static loads to minimize the occurrence of mechanical complications (Arcuri et al., 2020; Rungruanganunt et al., 2013). A passive fit with an accuracy of up to 150 μm is strongly advised (Jemt & Lie, 1995; Pozzi et al., 2022; Pradíes et al., 2014). However, a prosthetic misfit may lead to bacterial leakage and cause biological complications (Katsoulis et al., 2017); therefore, an accurate recording of the implant coordinates and prosthetic manufacturing are fundamental prerequisites (Aglietta et al., 2009; Pradíes et al., 2014).

The conventional implant impression workflow is still considered the gold standard for complete arches (Pozzi, Tallarico, Mangani, et al., 2013). However, several steps are necessary to produce the master cast, and each step is accountable for errors due to the intrinsic limitations of impression and pouring materials (Pozzi, Tallarico, Mangani, et al., 2013). The further need to digitize the master cast for computer-aided design–computer-aided manufacturing (CAD-CAM) makes the overall workflow even more challenging (Yan et al., 2022). To avoid these issues and shorten the overall digital workflow, an intraoral optical surface scanning (IOS) implant impression was introduced to record and directly digitize the implant positions (Peñarrocha-Diago et al., 2017).

Digital impressions are now considered a valid alternative to conventional impressions to record intraoral anatomy and implant positions (Amin et al., 2017; Rutkūnas et al., 2017). However, IOS implant impression accuracy has been proven reliable for single and short spam FDPs (Imburgia et al., 2017). Accuracy is defined by trueness and precision (ISO5725-1); trueness describes the conformity of measurements to the actual values, and precision describes the conformity of multiple repeated measurements (Flügge et al., 2016). The application of IOS for complete-arch implant impression is still considered controversial both in terms of accuracy and practicality, especially for the lower jaw (Arcuri et al., 2020; Revilla-León et al., 2021). The major limitation of the current IOS systems is intrinsic to the three-dimensional (3D) image reconstruction technology, which is based on the best-fit algorithm stitching process. Continuous reference points are necessary to speed up the stitching process and increase the matching accuracy of the acquired consecutive 3D images (Kihara et al., 2019; Pozzi et al., 2022). Consequently, different artificial landmark techniques have been proposed and tested positively in terms of accuracy but are not free of deviations and may be cumbersome (Huang et al., 2020; Pozzi et al., 2022).

Stereophotogrammetry (SPG) was reported as a different digital impression technology to simultaneously record 3D objects and their spatial relationship using points within photographic images captured by two stereo cameras (Gómez-Polo et al., 2018). SPG was first proposed by Lie and Jemt (1994) as a method to measure the misfit between implants and frameworks. The use of SPG was proven to be a reliable guided surgery technology to execute a digitally planned implant treatment by a stereo tracking algorithm linking the preoperative implant planning coordinates with the live-tracked drilling and positioning coordinates system (Pozzi, Arcuri, Carosi, et al., 2021). SPG digital impression can record only the implant coordinates, and no stitching process is needed; however, recording of the intraoral dental and gingival anatomy is not possible and must be integrated with an auxiliary impression (Agustín-Panadero et al., 2015).

In vitro studies analyzed SPG accuracy for complete-arch implant impressions reporting controversial results (Ma et al., 2021; Revilla-León et al., 2021).

To the best of our knowledge, this is the first in vivo prospective clinical trial whose primary aim was to investigate and compare the accuracy of IOS and SPG for complete-arch implant impression. The clinical performance of IOS and SPG was evaluated for each patient enrolled in the study with a paired comparison of the deviation differences. The secondary aim was to analyze the potential effect of the type of arch (maxilla vs. mandible) and number of implants (4 vs. 6) on SPG and IOS accuracy. The null hypothesis was that SPG and IOS would show equivalent accuracy.

2 | MATERIALS AND METHODS

Since November 2020, any patient, of both genders, aged 18 years or older and in need of complete-arch FDPs, was recruited and enrolled in the clinical study. Informed consent was obtained from each enrolled patient. The nature of the study, benefits, risks, and possible alternative treatments were widely commented on prior to inclusion in the study, as well as any follow-up evaluations needed. Patients were consecutively treated up to April 2021 in one rehabilitation center.

The clinical trial was approved by the ethical committee of the University of Rome Tor Vergata (Protocol number 203.20) and registered as clinical trial in ISRCTN (https://www.isrctn.com) with number ISRCTN12501259, conducted in compliance with the Declaration of Helsinki for biomedical research involving human subjects as amended in 2008 and according to the industry regulations (the International Conference for Harmonization Guideline for Good Clinical Practice and ISO14155). According to the university institution regulations, study data are in the university repository and are not publicly available to avoid compromising ethical standards and legal requirements. Peer review of empirical data was conducted by an independent examiner member of the scientific committee of the University of Rome Tor Vergata to confirm the quality of the shared data and to confirm that the data reproduce the analytic results reported in the paper: (1) sample sizes match, (2) the variables described in the article are present as fields in the data university repository, (3) data are complete; (4) data are properly labelled and described; (5) it has the appropriate metadata for the kind of data being shared; and (6) data are available on request from the corresponding author.

The following inclusion criteria were used: (1) medically healthy patients; (2) full-mouth bleeding and full-mouth plaque index lower than or equal to 25%; (3) bone height for at least 10-mm-long implants; (4) bone width of at least 5 and 6 mm for narrow (NP 3.75 mm) and regular (RP 4.3 mm) implants, respectively; (5) fresh extraction sockets with an intact buccal wall; (6) at least 4 and 5 mm of bone beyond the root apex in the mandible and maxilla; (7) minimal insertion torque of 45 Ncm; (8) minimal Implant Stability Quotient (ISQ) mean value of 64 on the day of the surgery; (9) same-day surgery and provisionalization; (10) screw-retained complete-arch FDPs supported by 4 and 6 implants in the maxilla and/or mandible; (11) ISQ mean value of 72 the day of the definitive impression; and (12) availability to attend regular follow-up visits. Exclusion criteria were general medical (American Society of Anesthesiologists, ASA, class III or IV) and/or psychiatric contraindications; pregnancy or nursing; any interfering medication such as steroid therapy or bisphosphonate therapy; alcohol or drug abuse; heavy smoking (>10 cigarettes/day), radiation therapy to head or neck region within 5 years, and untreated periodontitis; acute and chronic infections of the adjacent tissues or natural dentition; severe maxillomandibular skeletal discrepancy; high and moderate parafunctional activity; and absence of opposite teeth (Johansson et al., 2011).

One clinician for each center performed all the surgical and prosthetic procedures, and one dental laboratory experienced in CAD-CAM technology designed and manufactured the screw-retained zirconia ceramic implant-supported prostheses. This study is reported in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement for improving the quality of observational studies (http://www.strobe-statement.org; von Elm et al., 2014) (Supporting Information).

2.1 | Clinical and laboratory protocol

Before implant placement, all study participants received a comprehensive examination including a cone-beam computed tomography scan. The digital imaging and communication in medicine (DICOM) files were imported into the implant planning software program (DTXStudioImplant; Dexis). Implant planning was executed accurately according to a prosthetically and soft tissue-driven approach, positioning the two anterior implants parallel to each other and the two or four posterior implants angulated symmetrically with the same divergence with respect to the anteriors (Agliardi et al., 2012, 2023; Pozzi, Arcuri, et al., 2020). Conical connection implants (NobelActive, NobelParallel; NobelBiocare AG) were placed by means of computer-assisted static and dynamic-guided surgery (Pozzi, Hansson, et al., 2020). A digitally prefabricated multilayered polymethyl methacrylate (Whitepeaks; Whitepeaks Dental Solutions GmbH & Co) interim prosthesis was relined on temporary cylinders screwed at the abutment level (MUA abutment; NobelBiocare AG) and delivered on the day of the surgery. After an uneventful healing period of 3 and 4 months in the mandible and the maxilla, the provisional restoration was removed, and the implant stability quotient was measured. In the case of ISQ > 72, abutment-level impression copings were tightened onto the multiunit abutments at 15 Ncm, and a conventional definitive impression was made with an open-tray technique and plaster material (SnowWhite Plaster no. 2; Kerr) (Pozzi, Tallarico, Mangani, et al., 2013) (Figures 1 and 2). The master casts were poured from the conventional plaster impression in low expansion type IV dental stone (FujiRock EP; GC). The master cast were digitalized with a high-resolution laboratory scanner (D2000; 3Shape), with an accuracy of 5 µm, as specified by the International Organization for Standardization (ISO) standard 12836 to achieve digital master cast standard tessellation language (STL) file used as reference. International Organization for Standardization, ISO 9693-1 (Dentistry compatibility testing. Part 1: Metal–ceramic systems. Geneva: International Organization for Standardization; 2012. ISO Store Order: OP-184149 (Date: 2017-06-09). Available at: http://www.iso.org/iso/home.html). Then, an IOS impression was recorded with an intra-oral scanner (TRIOS4; 3Shape A/S) using implant scan bodies secured at the multiunit abutment level (Elos Accurate Multi-Unit; Elos Medtech) (Figure 3). The IOS device was a wireless pen-grip, powder-free scanner based on confocal microscopy laser technology with software version 1.4.7.5 calibrated right before the impression. The scan strategy was consistent for all the procedures following the manufacturer guidelines and starting from the most distal implant scan body on the patient's left side. The SPG system (Precise Implant capture, PiC camera, PiC dental) consisted of two charged couple device cameras designed and optimized for clinical use to identify specific scan bodies with single encoding secured onto the multiunit abutments (Figure 4). The SPG device has an infrared flash to eliminate shadow cast by ambient light, and the two cameras captured 10 extra-oral photographs per second with an error margin lower than 10 µm. Before the scan, each SPG scan body was identified according to its surface code, selected into the software, and screwed onto the multiunit abutments (Figure 5). The SPG system was positioned extra-orally, 15–30 cm from the patient's mouth, and with an angulation variable from 90° to 45° with respect

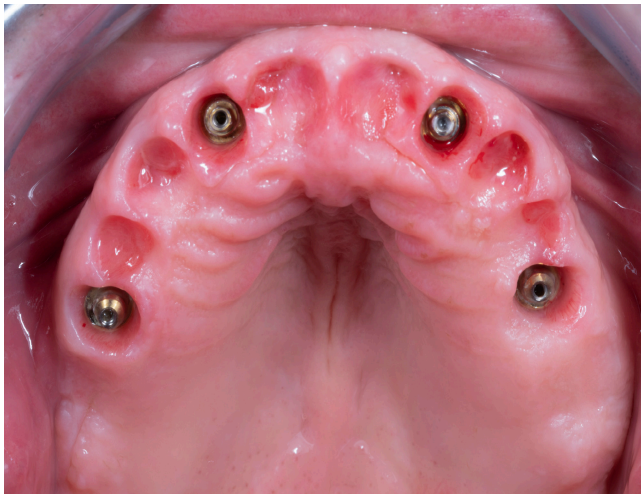

FIGURE 1 Scalloped soft-tissue profile of treated maxilla at definitive multiunit-level impression.

FIGURE 2 Plaster open-tray definitive impression.

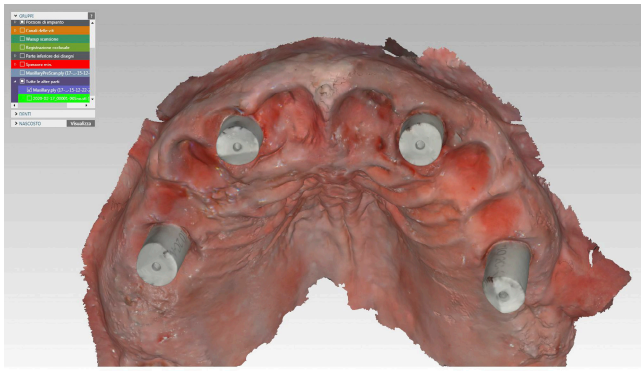

FIGURE 3 Intraoral optical scanning digital impression using implant scan bodies secured at the multiunit abutment level.

FIGURE 4 Clinical scenario of stereophotogrammetry system recording digital coordinates of specific scan bodies secured onto the multiunit abutments.

to the scan body surface to have all the SPG scan body geometries in the sight of the two stereo cameras (Figure 4). After internal system calibration, the images captured by the SPG system were processed, and the software algorithm extracted the relative angle and distance between each implant position in vector form. The SPG impression recorded only the vectorial relationship between the implant prosthetic platforms in an STL file (Figure 6) and had to be integrated with the soft-tissue information achieved by the IOS impression using a best-fit software algorithm (DTX StudioLab; Dexis).

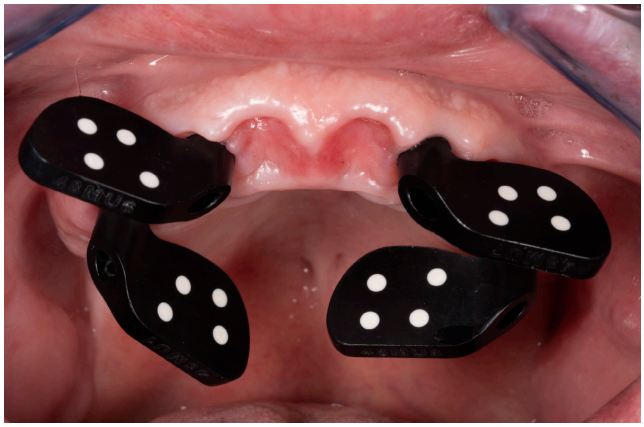

FIGURE 5 Intraoral view of the stereophotogrammetry scan bodies. Note that each scan body has a unique code that is provided by the position of the white dots on its surface.

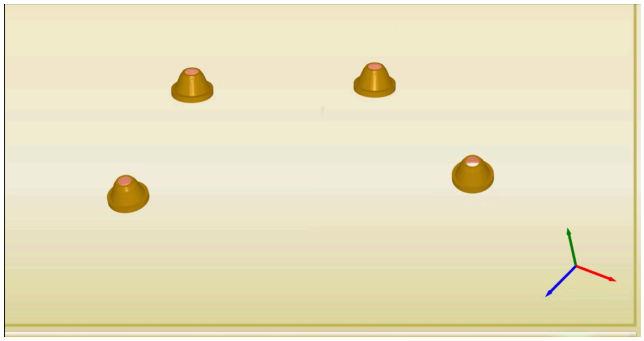

FIGURE 6 Implant prosthetic platforms standard tessellation language digital coordinates elaborated by stereophotogrammetry software after the digital impression.

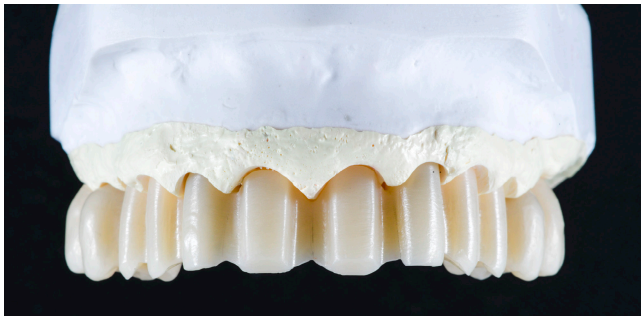

FIGURE 7 Implant-supported screw-retained zirconia-based complete-arch fixed-dental prostheses made by computer-aided design/computer-aided manufacturing procedures at the moment of accuracy and fit of assessment onto plaster master cast.

CAD-CAM implant-supported screw-retained zirconia-based complete-arch FDPs (ISZ-FDPs) were digitally designed onto master cast reference files, obtained from the plaster impression, and fabricated by centralized industrial production (NobelBiocare Procera LL) (Figure 7). The accuracy and fit of ISZ-FDP were first assessed onto the respective master cast using a dental laboratory microscope (Leica M50; Leica Microsistems) at 35× magnification and the

Sheffield one-screw test and then in the patient mouth according to established criteria, such as strain-free screwing, as well as no open margins at the clinical and radiographic examinations during the Sheffield one-screw test performed chair side (framework correctly in place without vertical and horizontal discrepancy at close-up inspection and periapical radiographs) (Figures 8a,b and 9) (Abduo et al., 2010; Kan et al., 1999; Pozzi, Arcuri, Fabbri, et al., 2021; Pozzi, Tallarico, & Barlattani, 2013).

2.2 | Data processing and accuracy assessment

All the ISZ-FDPs passed the accuracy and fit test. For each patient complete arch, three digital files were obtained: one reference scan (indirect digitalization of plaster impression) and two test scans (IOS and SPG digital impressions). The digital files including only the implant positions were then used for the accuracy analysis. The IOS and SPG test scans of each patient's complete arch were aligned to the relative reference scan with a Gauss best-fit algorithm (Geomagic Studio 12; 3DSystems), with an alignment tolerance of 0.01 mm, and two alignment optimizations were accomplished after file superimposition (Peroz et al., 2021). Linear (ΔX, ΔY, and ΔZ) and angular deviations (ΔANGLE) between the test scan and reference scan were measured for any implant position, analyzing the previously superimposed files by means of dedicated software (Hyper Cad S, Cam HyperMill, Open Mind Technologies). Negative values on the *X*, *Y*, and *Z* axes described an implant positioned left, downwards, and backwards, respectively (lateral, vertical, and longitudinal), while the positive values were in the opposite direction on each axis. Three-dimensional (3D) deviation was calculated for each implant position according to the Euclidean distance (ΔEUC).

2.3 | Statistical analysis

Assuming Euclidean distance as the primary endpoint and a significance level of .05, $n = 84$ was the minimum sample size able to guarantee, for a minimum expected difference of 120 μm (SD 150 μm), and a test power of 0.95. Sample size computation was based on paired *t*-test. The mean, SD, and minimum and maximum values were reported to summarize continuous variables. Differences between errors associated with the two devices (SPG-IOS) were computed for each implant with negative values expressing a benefit in terms of accuracy in favor of SPG. Their empirical distributions were obtained by Kernel density estimator; significance was evaluated by paired *t*-test. ANOVA was used to compare expected differences among the three groups. Box and Whisker plots were created to graphically compare empirical distributions. Multivariable analysis was based on the mixed linear model. Two different models were fitted assuming ΔEUC and ΔANGLE as response variables; logarithmic transformation was applied to improve normality. In both models, the fixed effects of scanning device (IOS vs. SPG), type of arch (maxilla vs. mandible), and supporting implant number (4 implants vs. 6 implants) were assessed. All analyses were undertaken using SAS software version 9.4 (SAS Institute) and R version 3.4.

3 | RESULTS

Eleven edentulous arches (five maxillae, six mandibles) in 11 patients were rehabilitated with screw-retained implant prostheses supported by 4 ($n = 8$) and 6 implants ($n = 3$) for a total amount of 50 implants. Implant positions were scanned by means of two digital devices (IOS and SPG) for a total of 100 implant positions recorded to be compared to the relative reference scans. Deviations were evaluated over the *Y*-, *X*-, and *Z*-axes, and angulation and stratified according to the scanning device (Table 1). Table 1 describes in detail the deviations from the reference scans of the IOS and SPG. The mean errors associated with the use of SPG are always less than those related to IOS except for ΔX. Note also the difference in terms of SD both on the linear and angular deviation in favor of SPG. For each implant, the difference between the ΔEUC associated with the two devices (SPG–IOS) was computed; the empirical distribution is shown in Figure 10. A mean difference of −49.60 μm (SD 138.15) was observed with a significant error reduction for SPG compared to IOS ($p = .0143$). The difference distribution was stratified by the type of arch and implant number (Figure 11). Note that no mandible with 6 implants is present in the sample. Although no significant difference was detected among

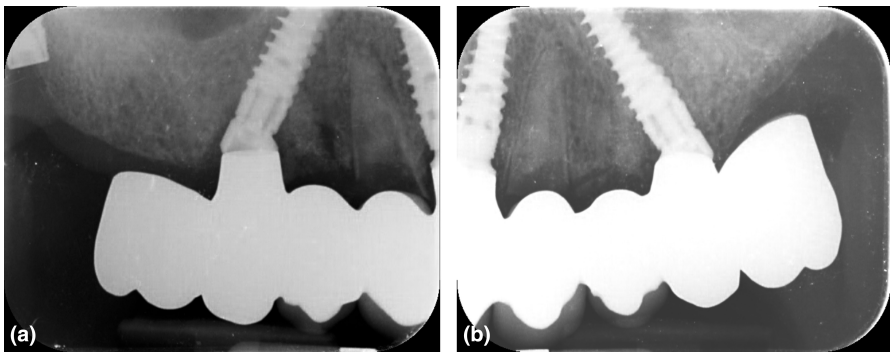

FIGURE 8 (a, b) Periapical radiographs to assess the correct fit of the ISZ-FDP in the patient's mouth during the Sheffield one-screw test. ISZ-FDP, implant-supported screw-retained zirconia-based complete-arch fixed-dental prostheses.

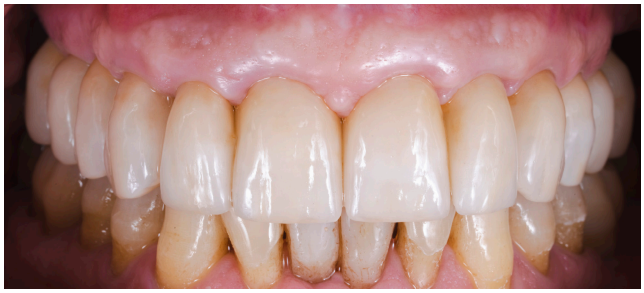

FIGURE 9 Clinical view after definitive restoration placement.

TABLE 1 Descriptive analysis of IOS and SPG linear, 3D, and angular deviations.

	Mean	SD	Min	Max
IOS				
Δ*X* (μm)	−19.8	110.2	−223	304.7
Δ*Y* (μm)	−4.1	44.3	−111.6	−147.1
Δ*Z* (μm)	−41.9	127.5	−536.3	177.6
ΔEUC (μm)	137.2	115.5	11.5	558.1
Angle (°)	0.79	0.59	0.05	2.89
SPG				
Δ*X* (μm)	−24.8	71.8	−192	113.8
Δ*Y* (μm)	−3.4	29	−173.8	50.8
Δ*Z* (μm)	20.9	79.1	−264	250.8
ΔEUC (μm)	87.6	74.2	12	316.2
Angle (°)	0.38	0.29	0.02	1.92

Abbreviations: IOS, intraoral optical scanning; SPG, stereophotogrammetry.

the three groups ($p = .5925$), three extreme differences were observed for mandible and 4 implants with impressive differences in favor of SPG (Table 2).

Considering the difference distribution for ΔANGLE (Figure 12), a mean deviation difference of −0.40° (SD 0.65°) was observed with a significant positive effect of SPG ($p < .0001$).

In the stratified analysis, no significant difference among groups was detected ($p = .2666$) (Figure 13).

Note that three extreme differences in angular accuracy were observed in favor of SPG of approximately −2.75, −1.90, and −1.62° (Table 3). In the multivariable analysis, two different mixed linear models were fitted, considering ΔEUC and ΔANGLE as response variables. In both models, the scanning device (IOS vs. SPG), type of arch (maxilla vs. mandible), and implant number (4 implants vs. 6 implants) were assumed as explanatory variables. The scanning device confirmed a significant effect on both ΔEUC and ΔANGLE; the *p*-values were .0162 and .0001, respectively (Tables 4 and 5). No significant effect was detected for the type of arch and supporting implant number. Note that in the case of ΔANGLE, parameter estimates for type of arch and implant number are close to 0, while for ΔEUC, both estimated effects and standard errors are consistent.

4 | DISCUSSION

The use of complete-arch digital implant impression is still controversial due to the current paucity of data, with only two in vivo studies comparing SPG and IOS technologies (Orejas-Perez et al., 2022; Yan et al., 2022). The primary objective of this single cohort clinical trial was to investigate and compare the accuracy of IOS and SPG for complete-arch digital implant impression. The secondary objective was to analyze the potential effect of the type of arch (maxilla vs. mandible) and number of implants (4 vs. 6) on SPG and IOS accuracy. The main limitation is that reported outcomes are inherent to the investigated IOS and SPG systems and shall be extrapolated with caution to any other device. However, the authors investigated one of the two SPG devices commercially available and one of the most widely published IOS in the scientific literature. Furthermore, one expert clinician performed all the scans, which may have unidentified some differences between the systems related to operator skill and experience. To the best of our knowledge, this is the first clinical trial assessing accuracy of complete-arch digital impressions executed with two investigated devices with sample size calculation and powerful statistics. An a priori sample size was difficult to define being the first study in vivo. Assuming Euclidean distance as the primary endpoint and a significance level of .05, it was computed a sample size of $n = 84$ as the minimum sample size able to guarantee, a minimum expected difference of 120 μm (SD 150 μm), and a test power of 0.95. During the study execution, it was able to increase the total sample to $n = 100$ (50 implant positions per device), corresponding to 11 complete arches (5 maxillae, 6 mandibles) in 11 patients analyzed in accordance with principles of good clinical practice and documented with no protocol deviations. Despite the relative low patient sample size, a total of three impressions (plaster, SPG, and IOS) was taken in each patient enrolled in the study, and the clinical performance of IOS and SPG was evaluated with a paired comparison of the deviation differences for each implant position. Even though sample size was limited, a non-significant test does not prove the absence of an effect, especially if of small magnitude. However, at multivariable analysis, it was able to identify a significant effect for the scanning device, after adjusting for type of arch and implant number. Similarly, an important effect of type of arch and implant number would have been detected if large in magnitude. Nevertheless, the sample was increased, the ratio between the number of patients and investigated variables (device, type of arch, and implant number) has to be considered as a limiting factor, and future research with a greater patient sample size is advised to further confirm the results achieved in the present study. The use of a certified 5 μm accuracy optical desk scanner as a reference, with its limitations, was justified by the better access to the freedom planes compared to tactile systems such as the coordinate measuring machine and because it is widely accepted as a laboratory procedure to digitize the plaster master cast (Mizumoto et al., 2020). The study design was based on the use of a Gauss best-fit alignment

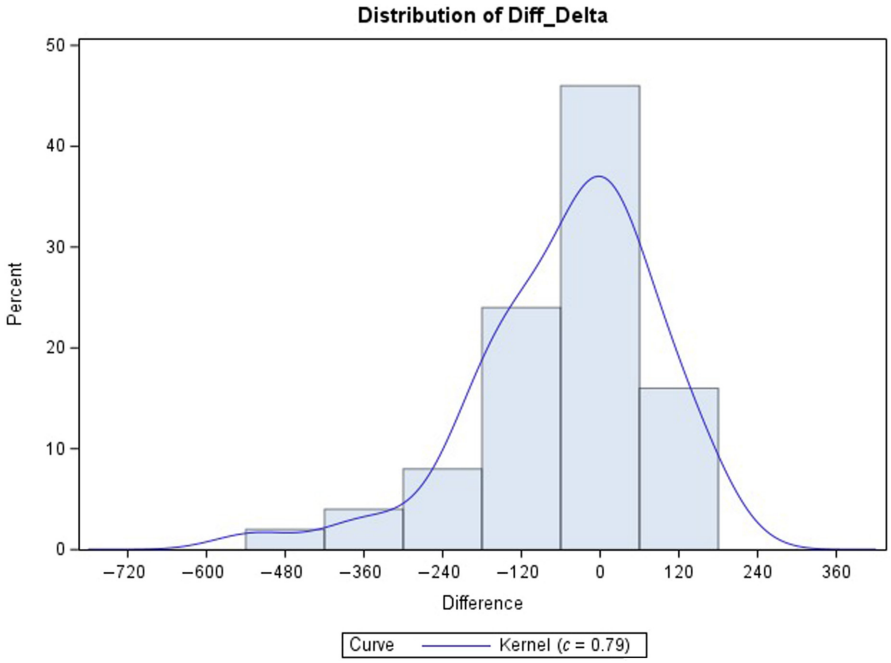

FIGURE 10 Empirical distribution of ΔEUC difference between stereophotogrammetry and intraoral optical scanning.

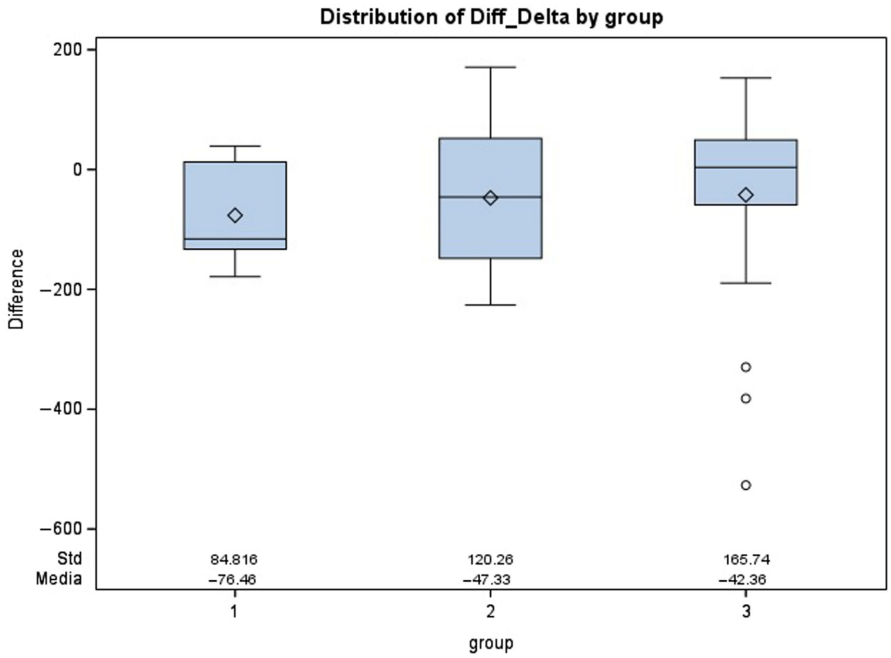

FIGURE 11 Distribution of ΔEUC difference between stereophotogrammetry and intraoral optical scanning according to type of arch and implant number: 1 = maxilla with 4 implants, 2 = maxilla with 6 implants, and 3 = mandible with 4 implants.

TABLE 2 ΔEUC extreme differences cases (μm).

Obs	SPG	IOS	ΔEUC difference	Patient	Arch	Support	Implant
24	31.2107	558.082	−526.871	5	Mandible	4 Implants	24
31	30.1874	359.980	−329.793	7	Mandible	4 Implants	31
39	25.7195	407.929	−382.209	9	Mandible	4 Implants	39

Abbreviations: IOS, intraoral optical scanning; SPG, stereophotogrammetry.

algorithm between the reference and test scans to measure the deviations for each implant position and to further analyze the 3D deviation in each of the three space axes. The Gauss best-fit algorithm, termed also iterative closest point alignment, allowed deviation measurement of all implant positions comparing the respected test and reference files and was proven to be a superior measurement method compared to other alignment algorithms (Peroz et al., 2021). In that way, it was possible to properly analyze the deviations of each implant from a linear (Δ*Y*, Δ*X*, Δ*Z*), 3D (ΔEUC), and angular point of view (ΔANGLE).

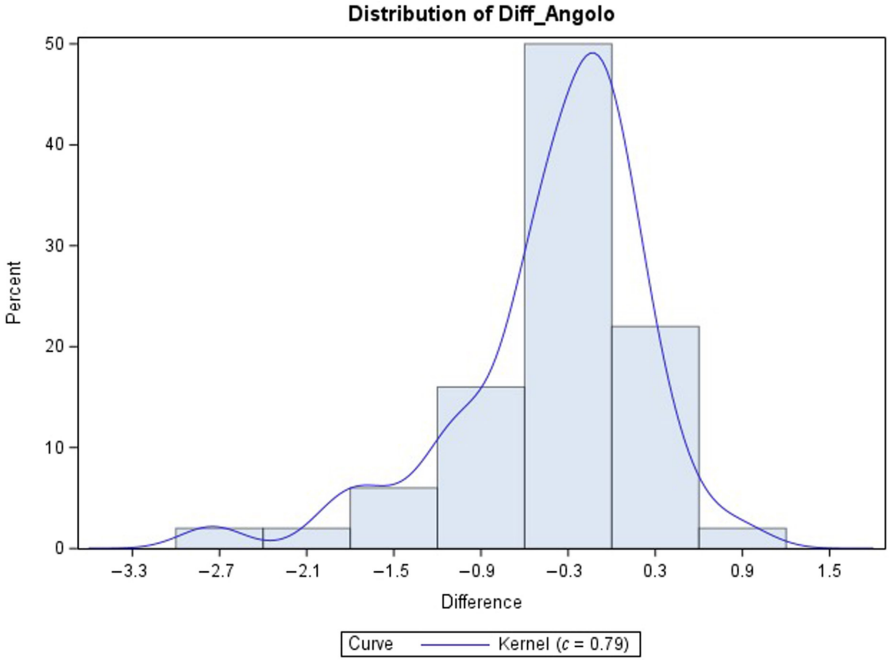

FIGURE 12 Empirical distribution of ΔANGLE difference between stereophotogrammetry and intraoral optical scanning.

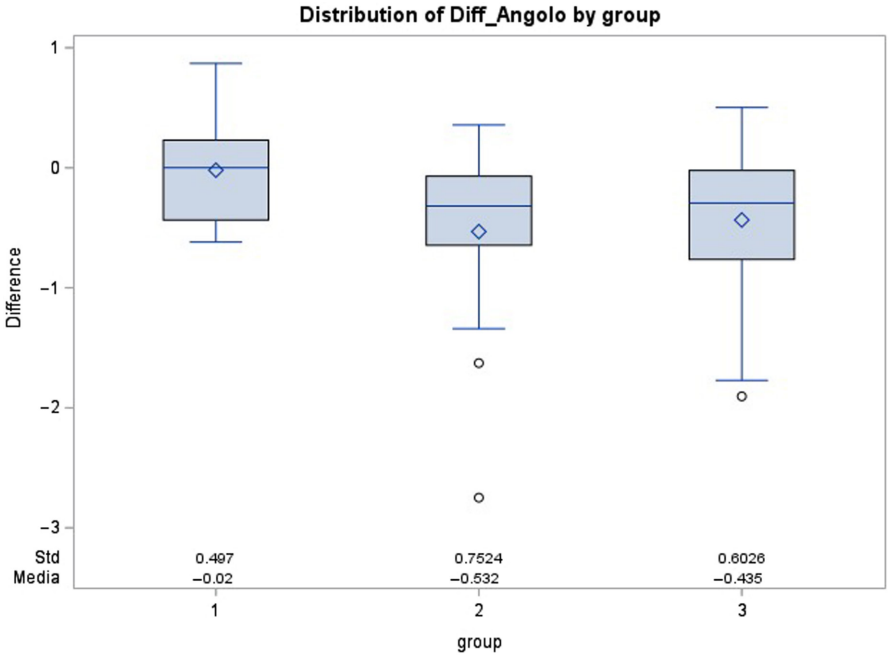

FIGURE 13 Distribution of ΔANGLE difference between stereophotogrammetry and intraoral optical scanning according to type of arch and implant number: 1 = maxilla and 4 implants, 2 = maxilla and 6 implants, and 3 = mandible and 4 implants.

TABLE 3 ΔANGLE extreme differences cases (°).

Obs	SPG	IOS	ΔAngle difference	Patient	Arch	Support	Implant
16	0.1419	2.8905	−2.7486	4	Maxilla	6 Implants	16
21	0.4563	2.0836	−1.6273	6	Maxilla	6 Implants	25
31	0.1397	2.0441	−1.9044	7	Mandible	4 Implants	31

Abbreviations: IOS, intraoral optical scanning; SPG, stereophotogrammetry.

The null hypothesis was rejected as SPG performed better than IOS both in terms of 3D (ΔEUC) ($p = .0143$) and angular deviations (ΔANGLE) ($p < .0001$). No effect of the type of arch (maxilla vs. mandible) or number of implants (4 vs. 6) on SPG and IOS accuracy was detected. Previous studies have evaluated the accuracy of various IOSs for complete-arch implant impressions, but a consensus has

TABLE 4 Estimates of fixed effects on ΔEUC (logarithmic scale).

Effect	Estimate	Standard error	*t*-Value	*F*-value	*p*-Value
Intercept	4.28	0.29			
Device (SPG vs. IOS)	−0.42	0.17	−2.45	6.02	.0162
Type of arch (mandible vs. maxilla)	0.31	0.32	0.98	0.96	.3294
Implant number (6 vs. 4)	0.36	0.34	1.06	1.12	.2926

Abbreviations: IOS, intraoral optical scanning; SPG, stereophotogrammetry.

TABLE 5 Estimates of fixed effects on ΔANGLE (logarithmic scale).

Effect	Estimate	Standard error	*t*-Value	*F*-value	*p*-Value
Intercept	−0.55	0.20			
Device (SPG vs. IOS)	−0.67	0.15	−4.48	20.10	<.0001
Type of arch (mandible vs. maxilla)	0.03	0.22	0.12	0.01	.9067
Implant number (6 vs. 4)	0.10	0.23	0.42	0.18	.6755

Abbreviations: IOS, intraoral optical scanning; SPG, stereophotogrammetry.

not been reached on the feasibility of this technique in the daily routine (Amin et al., 2017; Chochlidakis et al., 2020; Pesce et al., 2018; Treesh et al., 2018). Currently, there is no consensus regarding the range of acceptable misfits and the way to correctly measure the misfit clinically (Abduo, 2012; Katsoulis et al., 2017). However, a threshold value of 150 μm was suggested to avoid long-term complications such as loss of retention, screw loosening, fracture of framework, or veneering material (Jemt & Lie, 1995; Mericske-Stern & Worni, 2014; Schwarz, 2000). Moreover, the extreme values in terms of 3D and angular deviations of a single implant in a complete arch supported by 4 and 6 implants were established as 150 and 50 μm in the horizontal and vertical planes and 1° in terms of angulation (Manzella et al., 2016). Moreover, as the implant number increases, the tolerance of the error in the three axes and the angulations decrease (de França et al., 2017). Furthermore, we must consider the manufacturing tolerance of the prosthetic suprastructures that can generate misfits in the form of gaps between 20 and 100 μm (Ortorp et al., 2003). A recent in vitro study investigating the same SPG device reported SPG might be a clinically acceptable alternative to conventional complete-arch implant impressions. However, splinted elastomeric impression method obtained statistically significantly higher overall accuracy, with a trueness difference of 3 μm and a precision difference of 18 μm between the systems (Revilla-León et al., 2023). In the present study, the mean errors associated with the use of SPG were always less than those related to IOS but for the lateral axis (Δ*X*). The greatest difference was found on the longitudinal axis (Δ*Z*), with SPG experiencing 20.9 μm (SD 79.1) and IOS −41.9 μm (SD 127.5). Moreover, the overall 3D deviations in the three axes were significantly in favor of SPG with 87.6 μm (SD 74.2) versus 137.2 μm (SD 115.5) of IOS and far below the accepted threshold value to achieve long-term clinical prognosis of complete-arch implant-supported prostheses. In terms of angle, the mean deviation for each implant position was significant in favor of SPG with 0.38° (SD 0.29) versus 0.79° (SD 0.59) of IOS. The clinical meaning of this 0.40° angular deviation difference has to be further interpreted considering the overall number of implants for each complete arch. Moreover, the extreme differences recorded between the two investigated devices' deviations for each implant position was up to 2.7486° in favor of SPG. Such differences may advise the use of SPG as a more reliable alternative than IOS for complete-arch digital implant impression. Even though a rigid prototype try-in is still recommended before manufacturing definitive screw-retained complete-prostheses, similar outcomes were reported in a recent in vivo study related to two different IOS and SPG systems, whose clinical performance was not analyzed and compared in the same patient (Yan et al., 2022). SPG was more accurate than IOS (range 2.70–92.80 μm, median 17.00 vs. 21.30 to 815.60 μm, and median of 48.95 μm) and not affected by the position or number of implants. The passive fits of the prosthetic frameworks fabricated by SPG, and laboratory scanning were comparable. Another in vivo study analyzed the accuracy of two IOSs and one SPG device in both arches of a single patient. SPG reported the best repeatability in terms of interimplant distance and angular deviation. The type of arch did not affect the SPG accuracy, while the IOSs performed worse in the mandible (Orejas-Perez et al., 2022). In the present study, SPG achieved lower SD in all the linear, 3D and angular deviations than IOS.

The reported IOS means 3D and angular values may negatively affect the overall implant–prosthesis fit, while SPG performed significantly better in terms of 3D and angular deviations; thus, its clinical application for complete-arch digital impression is more advisable and feasible. It has to be considered that the reported deviations are related only to the impression process and therefore are not inclusive of the errors deriving from the other steps necessary to fabricate an implant-supported prosthesis. However, both systems reported extreme deviations far above the clinically accepted

threshold value (IOS 558.1 μm [ΔEUC] and 2.89° [ΔANGLE]; SPG 316.2 μm and 1.92°); therefore, SPG clinical application in a daily routine should be executed with caution, and a rigid prototype try-in is strongly recommended before manufacturing definitive screw-retained complete-arch prostheses. Further clinical investigations are necessary to record accurate data on a larger sample size, especially for the effect of type of arch and number of implants on ΔEUC. Moreover, the impact of the other production steps should be investigated to validate the investigated technologies and the related CAD-CAM workflow for producing screw-retained zirconia-based complete-arch FDPs.

5 | CONCLUSIONS

Within study limitations, SPG performed significantly better than intra-oral scanners with lower 3D and angular deviations and consistent performance. Higher extreme deviations were experienced for IOS. No effect of the type of arch or implant number was detected. SPG can be feasible for complete-arch digital impression. Its clinical application must be executed with caution, and a rigid prototype try-in is recommended before manufacturing definitive screw-retained complete-arch prostheses.

AUTHOR CONTRIBUTIONS

Alessandro Pozzi: Conceptualization; investigation; writing—original draft; methodology; validation; visualization; writing—review and editing; project administration; supervision; resources. **Paolo Carosi:** Conceptualization; investigation; writing—original draft; methodology; validation; visualization; writing—review and editing; project administration; supervision; resources; software; data curation. **German O. Gallucci:** Writing—original draft; writing—review and editing; supervision; conceptualization; methodology. **Katalin Nagy:** Writing—original draft; writing—review and editing; supervision; methodology; conceptualization. **Alessandra Nardi:** Formal analysis; software; data curation; conceptualization; writing—original draft; methodology; writing—review and editing; supervision. **Lorenzo Arcuri:** Conceptualization; investigation; writing—original draft; methodology; writing—review and editing; supervision; data curation; project administration.

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CONFLICT OF INTEREST STATEMENT

The authors have stated explicitly that there are no conflicts of interest to disclose in connection with this article.

DATA AVAILABILITY STATEMENT

According to the University Institution regulations on the clinical trials, study data are in the University repository and not publicly available to avoid compromising ethical standards and legal requirements. However, study data may be available on request from the corresponding author in respect of privacy and ethical restrictions.

ETHICS STATEMENT

The study was approved by the Ethical Committee of the University of Rome Tor Vergata protocol number 203/20.

PATIENT CONSENT STATEMENT

All involved participants gave their informed consent prior to study inclusion.

PERMISSION TO REPRODUCE MATERIAL FROM OTHER SOURCES

No permission to reproduce material from other sources was needed.

CLINICAL TRIAL REGISTRATION

University of Rome Tor Vergata Clinical Trial protocol number 203/20 and registered with the identifier ISRCTN12501259.

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