THE ACCURACY OF STEREOPHOTOGRAMMETRY FOR COMPLETE-ARCH DIGITAL IMPLANT IMPRESSION IN VITRO AND IN VIVO

Summary of the PhD thesis

by

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PUBLICATIONS PROVIDING THE BASIS OF THE THESIS

1. **Pozzi A,** Agliardi E, Lio F, Nagy K, Nardi A, Arcuri L. Accuracy of intraoral optical scan versus stereophotogrammetry for complete-arch digital implant impression: An *in vitro* study. *J Prosthod Res.* 2023 Aug 11. doi: 10.2186/jpr.JPR_D_22_00251. Epub ahead of print.

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2. **Pozzi A**, Carosi P, Gallucci GO, Nagy K, Nardi A, Arcuri L. Accuracy of complete-arch digital implant impression with intraoral optical scanning and stereophotogrammetry: An in vivo prospective comparative study. *Clin Oral Implants Res.* 2023 Jul 24. doi: 10.1111/clr.14141. Epub ahead of print.

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ABBREVIATIONS

ASA	American Society of Anaesthesiologists
CAD-CAM	Computer-Assisted Design and
	Computer-Assisted Manufacturing
CBCT	Cone-Beam Computed Tomography
CCD	Charged Couple Device camera
СММ	coordinate measuring machine
DICOM	imaging file type (also .dcm)
FDP	fixed dental prosthesis
GCP	Good Clinical Practice
IOS	intraoral scanner
ISB	intraoral scan body
ISO	International Organization for
	Standardization
ISRCTN	International Standard Randomized
	Controlled Trial Number
ISQ	Implant Stability Quotient (Osstell)
ISZ-FDP	implant-supported, screw-retained
	zirconia complete-arch fixed dental
	prosthesis
PMMA	polymethyl methacrylate
RMS	root mean square
SD	standard deviation
SPG	stereophotogrammetry
SPG ISB	intraoral scan body for the purposes of
	stereophotogrammetry
STL	stereolithography file type (also .stl)

I. INTRODUCTION

Achieving long-term successful outcomes for screwretained complete arch fixed dental prostheses (FDPs) relies on ensuring accurate matching between implants and frameworks. The primary objective is to deliver an FDP that exhibits proper fit with the prosthetic platforms, minimizing the occurrence of mechanical complication. It is strongly recommended to achieve a passive fit with an accuracy of up to 150 micrometers. In addition, a misfit between the prosthesis and implants may result in bacterial leakage and give rise to biological complications. Therefore, precise recording of implant coordinates and prosthetic manufacturing accurate are essential prerequisites.

The conventional approach for capturing implant impressions in complete arch cases is still widely regarded as the preferred method in complete-arch cases. However, this workflow involves multiple steps, which does not only make it time-consuming, but also carries the risk of the cumulation of error. Furthermore, the subsequent requirement to digitize the master cast for CAD-CAM further complicates the overall process. Finally, patients often find the conventional approach unpleasant, which obviously encourages the use of digital methods for impression taking.

Intraoral optical surface scanning (IOS) systems have emerged and become widespread as the digital alternative to conventional impressions for capturing intraoral anatomy and implant positions. However, while the accuracy of IOS implant impressions has been established for single and short-span fixed dental prostheses (FDPs), its application for complete arch implant impressions remains controversial, particularly for the lower jaw. The accuracy of intraoral scanning is influenced by various factors, including those related to the operator (such as scanning technology and system selection, scanning head size, calibration, scanning distance, exposure of the IOS to ambient temperature changes, ambient humidity, ambient lighting conditions, operator experience, scanning pattern, extension of the scan, cutting off, rescanning, and overlapping) and patient factors (including tooth type, presence of interdental spaces, variations in arch width, palate characteristics, wetness, existing restorations, characteristics of the surface being digitized, edentulous areas, interimplant distance, position, angulation, and depth of existing implants, and the type of the applied implant scan bodies). The main limitation of current IOS systems lies in their three-dimensional (3D) image reconstruction technology, which utilizes a best fit algorithm stitching process. To enhance the accuracy of consecutive 3D images, continuous reference points are essential to expedite the stitching process and improve matching accuracy. Various artificial landmark techniques have been proposed and tested positively in terms of accuracy, although they may introduce deviations and pose practical challenges.

Stereophotogrammetry (SPG) is a distinct digital impression technology that captures three-dimensional objects and their spatial relationship using points within photographic images from two stereo cameras. Initially proposed by Lie and Jemt as a method to measure the misfit between implants and frameworks, SPG has been

established as a reliable technology for digitally planned, dynamically guided implant treatment as it utilizes a stereo tracking algorithm that can connect preoperative implant planning coordinates with live-tracked drilling and positioning coordinates. SPG allows the recording of the implant coordinates without the need for stitching, like in the case of IOSs. However, it cannot capture intraoral anatomy, which dental and gingival necessitates integration with an auxiliary impression. A further relative drawback is that the global market currently offers a limited number of SPG devices, and their cost surpasses that of IOS systems. The first randomized, controlled clinical trial to establish if SPG might be suitable for digital impression taking for FDPs was published in 2017 by Peñarrocha-Diago and co-workers and concluded that digital impressions using stereophotogrammetry may be an alternative to traditional impressions.

In vitro studies analyzed SPG accuracy for complete arch implant impressions reporting controversial results, and so far we know of only a pilot clinical trial that tested SPG for such purposes. While the overall picture is promising, we have too little evidence on the accuracy of SPG for complete arch implant impressions. This is why our research group decided to examine this question both *in vitro* and *in vivo*, in comparison to the most widespread digital impression technology: IOS. The comparison was logical not only because both approaches are digital, but also because SPG promises to overcome the shortcomings of IOS for this specific indication.

II. OBJECTIVES AND HYPOPTHESES

In this thesis, two studies are covered. Both dealt with the accuracy of SPG for complete arch implant impressions, and whether SPG is in fact superior to IOS in this indication.

The first study (Pozzi et al., 2023, *JProsthodRes*) examined these questions *in vitro*. The purpose was to assess and compare accuracy of an intraoral scanner (IOS) and a stereophotogrammetry (SPG) device for completearch digital implant impressions. A 4-analog mandible model was digitized with a desk scanner to achieve a reference file. Thirty test scans were recorded with an IOS and further 30 with an SPG device. The scans were then aligned to the reference file to calculate deviations. The null hypothesis was that no significant difference would be found in the 3D and angular deviations between the investigated complete-arch digital implant impression techniques.

The second study (Pozzi et al., 2023, *Clin Oral Implants Res*) examined the same questions *in vivo*, in a clinical population. The study recruited patients who required implant-supported screw-retained zirconia complete-arch fixed dental prostheses (ISZ-FDP). For each patient, both IOS and SPG scans (test impressions), and open-tray plaster impressions (reference) were taken. A total of 50 implants (100 images) were captured by the 2 investigated devices and compared to the reference. The study examined the same parameters of deviation as the *in vitro* study. The null hypothesis was that SPG and IOS would show similar accuracy, without significant difference between the devices.

III. METHODS

III.1. Methods of the *in vitro* study

milled Α edentulous mandible model made of polymethylmetacrylate (PMMA) was created, featuring four multiunit implant analogs (MUA, NobelBiocare, Switzerland). These analogs were positioned at the specific locations of teeth 32, 35, 42, and 45. The implant positioning followed the following criteria: tooth 32 (with a depth offset of -1 mm and a distal angulation of 5°), tooth 35 (with a depth offset of -3 mm and a mesial angulation of 10°), tooth 42 (at a depth of 0 mm and an angulation of 0°), and tooth 45 (with a depth offset of -4 mm and a distal angulation of 15°). To ensure the accurate fit of scanbodies (ISBs) on the model and to allow for fit verification, a removable soft tissue frame was 3D printed using specialized material (Gingiva Mask, NextDent) on a NextDent 5100 printer from 3D Systems in the USA, based in Rock Hill, SC.

To generate the reference scan, a D2000 dental laboratory scanner (3Shape, Copenhagen, Denmark), which had undergone meticulous calibration before the scanning process, was employed. The purpose was to obtain an .stl file that would serve as the designated reference. This scanner holds certification attesting to its accuracy level of 5 μ m.

An experienced operator, who remained unaware of the study's objectives, was enlisted for both scanning

instruments. Another operator was responsible for affixing the polyether ether ketone (PEEK) ISBs onto the MUA implant analogs. This attachment was achieved using a dynamometer-controlled torque of 10 Ncm. To ensure proper seating of the ISBs over the analog heads, visual verification was performed with magnifying loupes (Eyezoom 5X, Orascoptic, located in Middleton, WI, USA). Following this step, the same operator proceeded to affix SPG scanbodies onto the MUA implant analogs using an identical procedure. The process culminated in a total of 60 comprehensive arch scans, with 30 scans executed for each of the two scanning devices.

For the intraoral scans, we used iTero Element 5D (Align Technology, Tempe, AZ, USA). This is a pen-grip style scanner, which operates without the need for powder and functions through parallel confocal imaging laser technology. During the IOS scanning process, each scan was separated by a rest interval of at least 5 minutes. Commencing at ISB position 45 and concluding with 35, the scan sequence was consistently maintained. Before initiating the investigation, calibration of the IOS device was executed by the manufacturer.

The scan strategy remained uniform across all scanning procedures, adhering to the recommendations provided by the manufacturer. The scanning process commenced from the occlusal-lingual surface of ISB 45, progressed to include both surfaces of each ISB, and concluded by returning from the buccal side.

For the stereophotogrammetric recording of implant positions, the Precise Implant Capture system (PIC Dental, Madrid, Spain) was used. The SPG ISBs were affixed onto the multiunit abutments, and the software recorded the specific SPG code associated with each implant site. The SPG camera was positioned at an angle of 45° and situated between 15 to 30 cm away from the model. The SPG device captured images, which were then processed through the SPG software to derive the three-dimensional each implant coordinates of in vector format. Subsequently, an .stl file was generated and exported.

The alignment of the 60 test STL files with the reference scan was executed using specialized software (Geomagic Studio 12, 3DSystems, Rock Hill, SC, USA) with a precision of 0.01 mm for alignment tolerance. Two alignment optimizations were performed subsequent to file superimposition. Employing the best fit method, the superimposition between scans of the test and control groups and the reference scan was achieved. This approach took into account only the implant positions for alignment, mimicking a typical clinical and laboratory workflow.

For evaluating the deviations, a best fit algorithm was adopted to gauge the variance of each implant in comparison to its counterpart in the reference file. This enabled a comprehensive analysis of the 3D linear and angular deviations for each implant, encompassing the distribution of errors across the three-dimensional coordinates. Subsequently, dedicated measurement software (Hyper Cad S, Cam HyperMill, Open Mind Technologies, Milano, Italy) was employed to measure the linear (ΔX , ΔY , and ΔZ) and angular ($\Delta ANGLE$) discrepancies between each test scan and the reference scan for each analog. This measurement was conducted after reconstructing the linear geometries of the analogs, utilizing the centers of the digital analog heads as the reference points for deviation measurement.

Negative values along the X, Y, and Z axes indicated an ISB positioned to the left, downward, and backward, respectively, while positive values signified the opposite direction along each axis. The calculation of 3D deviations involved determining the Euclidean distance between the centers of the head of the test and control implant analogs (Δ EUC).

III.2. Methods of the clinical study

This clinical trial received ethical approval from the University of Rome Tor Vergata's ethical committee (Protocol No. 203.20) and was officially registered as a clinical trial in the ISRCTN registry (Reg.No. ISRCTN12501259). The trial was conducted in accordance with the principles outlined in the Declaration of Helsinki as amended in 2008 and adhered to the tenets of GCP.

Starting from November 2020, the clinical study aimed at recruiting and enrolling patients, aged 18 years or older, of both genders, who required complete arch fixed dental prostheses (FDPs), provided they met the eligibility criteria (see in thesis).

Each enrolled patient provided informed consent after receiving detailed information about the study's nature, potential benefits, associated risks, and alternative treatment options. Moreover, patients were fully informed about any required follow-up assessments before being included in the study. The recruitment of patients continued in succession until April 2021, all of whom were treated at a single rehabilitation center.

A single clinician executed all surgical and prosthetic procedures. Prior to the placement of implants, a comprehensive examination was administered to all participants in the study, which included a CBCT scan. The DICOM files resulting from the scan were imported into the implant planning software program (DTX Studio Implant, Dexis).

The implant planning process followed a meticulous approach that was both prosthetically and soft tissue driven. For the two anterior implants, a parallel positioning was ensured, while the 2 or 4 posterior implants were symmetrically angulated with consistent divergence compared to the anterior implants, in accordance with previous works [44-46].

Implant placement was carried out using conical connection implants (NobelActive, NobelParallel, NobelBiocare AG) with computer-assisted static and dynamic guided surgery methods [47]. An interim prosthesis made of digitally prefabricated multilayered polymethyl methacrylate (PMMA) (Whitepeaks, Whitepeaks Dental Solutions GmbH & Co.) was relined onto temporary cylinders that were screwed at the abutment level (MUA abutment, NobelBiocare AG). This interim prosthesis was delivered on the same day as the surgery. After a smooth healing period of 3 to 4 months, the provisional restoration was removed, and the implant stability quotient (ISQ) was evaluated.

In cases where the ISQ exceeded 72, abutment-level impression copings were securely fastened onto the multiunit abutments at a torque of 15 Ncm. A traditional definitive impression was then obtained using an open tray technique, employing plaster material (SnowWhite Plaster no. 2, Kerr).

The conventional plaster impressions were utilized to create master casts, which were then digitally converted into high-resolution .stl files. This conversion adhered to ISO 12836 standards and involved the use of a laboratory scanner (D2000, 3shape) with a precision of 5 μ m. These digital master cast .stl files were established as reference.

The intraoral scans were performed using the TRIOS4 intraoral scanner (3Shape A/S), a wireless powder-free pen grip device utilizing confocal microscopy laser technology. The intraoral scanner was calibrated immediately prior to the scan. The scan employed implant scan bodies (Elos Accurate Multi-Unit; Elos Medtech) secured at the multiunit abutment level. The scanning approach was consistent across all procedures, following

the manufacturer's guidelines, and initiated from the furthest ISB on the patient's left side.

The SPG system (Precise Implant capture, PIC camera, PIC dental) utilized two CCD cameras designed for clinical use to identify surface-encoded scan bodies secured onto the multiunit abutments. As discussed under I.2., these cameras capture 10 extraoral photographs per second with an error margin $< 10 \,\mu$ m. Before the scan, the SPG scanbodies were identified according to their surface code, registered in the software, and screwed onto the multiunit abutments. The SPG system was positioned outside the patient's mouth, approximately 15 to 30 cm away, at variable angles between 90° and 45° with respect to the scan body surface. This ensured comprehensive visibility of all SPG scan body geometries to the stereo cameras. Following internal system calibration, the captured SPG system images underwent processing. The software algorithm extracted the relative angles and distances between each implant position in vector form. The outcome of the SPG impression was an STL file that exclusively represented the vectorial relationship among the implant prosthetic platforms. To complete the overall information, this SPG data needed to be merged with the soft tissue details acquired from the IOS impression. This integration was achieved using a best-fit software algorithm (DTX StudioLab, Dexis).

For every patient's full arch, three digital files were procured: one served as a reference scan, achieved through the indirect digitalization of the plaster impression, and two functioned as test scans (obtained through IOS and SPG digital impressions). These digital files exclusively encompassing the implant positions were subsequently employed for the precision analysis.

The test scans acquired from both IOS and SPG methods for each patient's complete arch were meticulously aligned to the corresponding reference scan utilizing a best-fit algorithm (Geomagic Studio 12, 3DSystems, Rock Hill, SC, USA). The alignment process adhered to a tolerance of 0.01 mm, and two alignment optimizations were performed post file superimposition.

Zirconia-based complete arch fixed dental prostheses (ISZ-FDPs), supported by implants and retained with screws, were digitally designed using master cast reference files. These reference files were obtained from plaster impressions and the ISZ-FDPs were subsequently manufactured through centralized industrial production (NobelBiocare Procera LL).

To evaluate precision and fit, the ISZ-FDPs were initially examined on their respective master casts using a dental laboratory microscope (Leica M50, Leica Microsystems) at 35x magnification. This assessment was complemented by the Sheffield one-screw test. Subsequently, clinical evaluations were conducted in the patient's mouth, adhering to established criteria. These criteria included strain-free screwing and the absence of open margins, both confirmed during the chair-side Sheffield one-screw test. This examination encompassed close-up inspections and periapical radiographs, ensuring the proper placement of the framework without vertical or horizontal discrepancies.

Linear discrepancies (ΔX , ΔY , and ΔZ) as well as angular variations ($\Delta ANGLE$) between the test scan and reference scan were meticulously measured for every implant position. The analysis involved scrutinizing the previously superimposed files utilizing dedicated software (Hyper Cad S, Cam HyperMill, Open Mind Technologies, Milano, Italy). In terms of the X, Y, and Z axes, negative values indicated an implant situated towards the left, downward, and backward respectively (denoting lateral, vertical, and longitudinal directions). Conversely, positive values represented the opposing direction along each axis. A comprehensive three-dimensional (3D) deviation was then calculated for each implant position, employing the Euclidean distance (ΔEUC) as the determining factor.

IV.1. Results of the in vitro study

Deviation analysis involved comparing the reference scan with 60 test scans (30 IOS, 30 SPG) for each of the 240 implant analogs. This assessment encompassed deviations along the X, Y, and Z-axes, as well as angular discrepancies. The linear disparities were utilized to compute the 3D deviation using ΔEUC , irrespective of error direction.Notably, IOS exhibited elevated 3D mean ΔEUC in comparison to SPG (52.8 µm vs. 33.4 µm, p < 0.0001), with extreme values reaching up to 181.9 µm. It is pertinent to mention that IOS displayed a significantly higher standard deviation (SD) compared to SPG (37.1 µm vs. 17.7 μ m, p<0.0001). Implant site 45 emerged as the most critical when scanned with IOS (deviations up to 181.88 µm), whereas anterior implants (42 and 32) were more sensitive to SPG scanning. The reduction in 3D variability was significantly more prominent for SPG across all implants, except 42, where the reduction did not reach statistical significance.

Exploring Δ ANGLE, IOS exhibited slightly higher mean deviations than SPG (0.28° vs. 0.24°, p=0.0022), featuring extreme measurements of up to 0.73°. The SD values for SPG were notably smaller than those for IOS (0.14° vs. 0.04°, p<0.0001). Marginal discrepancies were identified related to implant position. The anticipated angular discrepancy differed significantly between IOS and SPG only for implant 42 (0.40° vs. 0.23° , p<0.0001). However, it is noteworthy that SPG consistently exhibited superior performance to IOS in terms of SD.

IV.2. Results of the clinical study

Eleven patients with edentulous arches underwent rehabilitation with screw-retained implant prostheses, with 5 cases involving maxillae and 6 involving mandibles. A total of 50 implants were employed, supported by either 4 (n=8) or 6 implants (n=3). In total, 100 implant positions were scanned using two digital devices (IOS and SPG) and compared to reference scans.

It is noteworthy that, with the exception of ΔX , mean errors associated with SPG were consistently lower than those linked to IOS. A notable discrepancy can also be observed in terms of standard deviation, favoring SPG for both linear and angular deviations. For each implant, the discrepancy between Δ EUC values associated with the two devices (SPG - IOS) was computed. This analysis revealed a mean difference of -49.60 µm (SD 138.15), indicating a significant reduction in errors for SPG compared to IOS (p = 0.0143).

As for \triangle ANGLE, an average deviation difference of -0.40° (SD 0.65°) was observed, signifying a significantly positive impact of SPG (p < 0.0001). Upon stratified analysis, no noteworthy distinctions were found among the groups (p = 0.2666).

The multivariable analysis employed two distinct mixed linear models, with Δ EUC and Δ ANGLE as dependent variables. Both models considered the scanning device (IOS vs SPG), arch type (maxilla vs mandible), and implant number (4 implants vs 6 implants) as independent variables. Notably, the scanning device exhibited a significant impact on both Δ EUC and Δ ANGLE, with p-values of 0.0162 and 0.0001, respectively. Conversely, no significant effects were detected for arch type or implant number.

V. CONCLUSIONS

Through the studies covered in this thesis, we have demonstrated the following novel scientific findings, which are directly related to the work that has been accomplished. It was found that:

- 1. Stereophotogrammetry (SPG) exhibited significantly higher 3D and angular accuracies compared to intraoral scanners (IOS) both *in vitro* and *in vivo*.
- 2. SPG outperformed IOS with higher precision, reduced deviations, and consistent performance both *in vitro* and *in vivo*.
- 3. SPG displayed consistent measurement repeatability in both settings both *in vitro* and *in vivo*.
- 4. IOS exhibited extreme deviations exceeding clinically acceptable thresholds both *in vitro* and *in vivo*.
- 5. *In vivo*, the type of arch (i.e., mandible or maxilla) or the number of implants (4 or 6) did not have a significant effect on the outcomes, regardless of whether SPG or IOS was used for the digital impressions.

findings, Based these conclude on we that stereophotogrammetry appears to be more feasible than IOS for complete arch digital implant impressions, as the reported IOS deviations may negatively affect the overall implant-prosthesis fit, particularly in screw-retained complete-arch restorations. Nonetheless, its clinical implementation demands careful consideration, with emphasis on the prudent execution of a rigid prototype tryin before proceeding to manufacture definitive screwretained complete-arch prostheses.

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