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Comparing the accuracy of Intraoral scanning (IOS) versus stereophotogrammetry (SPG) for impressions of dental implants for toothless patients

Submission date 22/03/2021	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 13/10/2021	**Overall study status** Completed	
Last Edited 04/10/2021	**Condition category** Oral Health	

Plain English summary of protocol

Background and study aims
The purpose of this project is to compare the accuracy of two digital impression techniques that can be used to create dental prosthetics to replace missing teeth. Defining the level of accuracy of these technologies will allow dentists to improve the workflow for creating these prosthetics and reduce the discomfort for patients. Traditionally these prosthetics are created using a plaster impression of the mouth which is then used as a mould to create the prosthetic. The ongoing development of digital technologies led to a more accurate and sophisticated way to achieve the exact 3D position of dental implants even in completely toothless jaws. Intraoral digital optical scanning (IOS) has been claimed as an alternative to the conventional implant impression even though the complete-arch implant impression by means of IOS is still considered one of the most challenging. Stereophotogrammetry (SPG) technology uses a double stereo camera to detect where the scan bodies are positioned.

Who can participate?
Healthy adults requiring a complete-arch implant-supported fixed dental prosthesis (FDP) of the upper and lower jaw

What does the study involve?
Eligible participants will have a plaster implant impression made of the area of their mouth where the teeth are missing and so a prosthetic is required. A plaster implant impression is currently considered the gold standard for this procedure and will be used to make the models for the prosthetic to be produced. Following this digital impressions will be taken using both SPG and IOS techniques to scan the mouth. The digital impressions will be compared by the researcher.

What are the possible benefits and risks of participating?
It is hoped that this study will benefit future patients by improving the prosthetic workflow and reducing patient discomfort.

Participation in the study is completely voluntary and participants can withdraw at any time.

Where is the study run from?
Policlinico Tor Vergata (Italy)

When is the study starting and how long is it expected to run for?
From January 2021 to October 2021

Who is funding the study?
Investigator-initiated and funded

Who is the main contact?
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Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Version 01

Study information

Scientific Title
Intraoral scanning (IOS) versus stereophotogrammetry (SPG) for complete-arch implant impression: A prospective in vivo study on 15 edentulous jaws

Acronym
IOSVSSPG

Study objectives
To assess the accuracy of IOS and stereophotogrammetry for complete-arch implant impressions in vivo.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 28/10/2020, Independent Ethical Committee Policlinico Tor Vergata (Viale Oxford, 81, 00133 Roma RM, Italy; +39 06-2090 0035; alessandra.nistri@ptvonline.it), ref: 203.20

Study design
Interventional non-randomized study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

See additional file

Health condition(s) or problem(s) studied
Implant-supported complete arch restorations of edentulous jaw

Interventions
The recruited patients of our study received a full-arch implant supported rehabilitation by means of a screw-retained fixed prosthesis in the last 3 years. After the Ethical Committee approval we scanned with IOS and with SPG the patients and obtained STL files, which have been analyzed and superimposed in order to obtain accuracy data. There will be no follow-up of patients.

Assuming Euclidean distance as primary measure of discrepancy, the aim of this study will be to determine whether stereophotogrammetry significantly increases the expected accuracy in comparison to IOS.

Reference scan:
Implant transfers were screwed onto the implants and gypsum impressions were taken. Consequently, the impressions were poured and digitized by means of a structured blue light 3D optical desk scanner (E4, 3Shape, Copenaghen, Denmark) with a declared accuracy of 4 μm (ISO 12836), properly calibrated before the scanning, in order to achieve a standard tessellation language (STL) file to be used as reference. The digital file obtained was used also as a master model for the definitive complete-arch rehabilitation.

Test scans:
The IOS device investigated was a cabled pen grip (Trios3, 3Shape A/S, Copenhagen, Denmark) with the software version 1.6.10.1. It is a powder-free scanner, based on confocal microscopy laser technology. The SPG device investigated was The PICcamera® (PICdental, Madrid, Spain) is a stereo-camera that records implant positions in the mouth by means of photogrammetry. It comprises two CCD cameras specially designed and optimized for clinical use, which accurately determine the position of the implants by means of the identification of abutments screwed on implants with unique individual coding (PICabutment®, PICdental). One operator, an expert in digital impressions recorded 2 impressions with the IOS and the SPG on each patient according to the guidelines of the device producers.

Data processing and accuracy assessment:
The 30 test STL files were aligned to the reference scan with dedicated software (Geomagic Studio 12, 3DSystems, Rock Hill, SC, USA), according to a 0.01 mm alignment tolerance, and 2 alignment optimizations were accomplished after the file superimposition. At last, linear and angular deviations between each test scan and the reference scan were measured for any analogue, analyzing the previously superimposed files through a dedicated measurement software (Hyper Cad S, Cam HyperMill, Open Mind Technologies, Milano, Italy). Linear deviations were assessed for each analogue on the three space axis (X longitudinal, Y lateral, and Z vertical). Negative and positive values depend on the alignment of each test scan with the reference scan and, considering the reference axis system used, must be interpreted as follows: negative values on the X, Y, and Z axis featured a scan body positioned frontward, left, and downward respectively, while the positive ones are in the opposite direction on each axis. 3D deviation was calculated using Euclidean distance. Angular deviations were assessed as the angles formed by the two lines passing perpendicularly through the centers of the test image and the reference image of each implant.

Intervention Type

Device

Phase
Not Applicable

Primary outcome measure
Accuracy measured by analyzing linear and angular deviations between each test scan and the reference scan using a dedicated measurement software (Hyper Cad S, Cam HyperMill, Open Mind Technologies, Milano, Italy)

Secondary outcome measures
The effect of stereophotogrammetry versus IOS, adjusting for possible confounding factors, will be measured using the General Linear Model at multivariate analysis

Overall study start date
08/01/2021

Completion date
15/10/2021

Eligibility

Key inclusion criteria
1. Healthy patients aged ≥18 years
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 mm and 6 mm for narrow (NP 3.75/3.5 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

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
15 arches (84 implants)

Key exclusion criteria
1. General medical (American Society of Anesthesiologists, ASA, class III or IV) and/or psychiatric contraindications

2. Pregnancy and/or breastfeeding
3. Any interfering medication such as steroid therapy or bisphosphonate therapy
4. Alcohol and/or drug abuse
5. Heavy smoking (>10 cigarettes/day)
6. Radiation therapy to head or neck region within 5 years
7. Untreated periodontitis
8. Acute and chronic infections of the adjacent tissues or natural dentition
9. Severe maxillomandibular skeletal discrepancy
10. High and moderate parafunctional activity
11. Absence of opposite teeth

Date of first enrolment
29/03/2021

Date of final enrolment
30/05/2021

Locations

Countries of recruitment
Italy

Study participating centre
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Sponsor type
University/education

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ROR
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Funder(s)

Funder type
Industry

Funder Name
Itesi s.r.l.

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
15/10/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from the corresponding author Paolo Carosi (Paolo.carosi@alumni.uniroma2.eu) as raw data from the publication date of the article for 1 year.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		09/12/2019	04/10/2021	No	Yes