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# Accuracy of digital impressions for dental implant crowns

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| **Submission date**<br>16/01/2023 | **Recruitment status**<br>No longer recruiting | [X] Prospectively registered<br>[X] Protocol<br>[_] Statistical analysis plan<br>[_] Results<br>[_] Individual participant data<br>[_] Record updated in last year |
| **Registration date**<br>14/11/2023 | **Overall study status**<br>Completed | |
| **Last Edited**<br>14/11/2023 | **Condition category**<br>Oral Health | |

## Plain English summary of protocol

Background and study aims
In recent decades, implant restorations for replacing missing or problematic teeth have become safer and more predictable due to advancements in dental technology. Digital tools, such as intraoral scanners and a photogrammetry-based system called Pic Dental®, have revolutionized implant procedures. While intraoral scanners offer a comfortable and precise alternative to traditional methods, they still have limitations. On the other hand, Pic Dental® utilizes a dual camera system and coded attachments for accurate implant position recording, overcoming many of the challenges associated with intraoral scanners. The study aims to assess the effectiveness of both approaches in achieving a passive fit for implant-supported restorations or crowns.

Who can participate?
Patients with implants placed in the clinics participating in the study who are waiting for impression taking or registration to make and place an implant-supported crown

What does the study involve?
Participants are randomly allocated to the test group or the control group. After the integration period, periodontal maintenance will be performed and the researchers will take a periapical (2D) radiograph. After this radiograph the healing abutment will be removed and the prosthetic abutment will be placed. Then, those participating in the test group will receive PIC transfers on their prosthetic abutments and registration will be performed with a PIC dental camera. In the control group, scan bodies will be placed on their prosthetic abutments and registration will be performed with an intraoral scan. After 10-15 days, an implant-supported restoration or crown will be placed and a new periapical radiograph will be obtained. Then, 6-month and 12-month follow-up visits will be performed with clinical, radiographic and patient-reported outcomes.

What are the possible benefits and risks of participating?
The benefit of participating is obtaining the most precise/accurate passive fit in implant-supported crowns. There is no additional risk of participating because it is a routine prosthetic procedure without risks.

Where is the study run from?
Periocentrum Bilbao (Spain)

When is the study starting and how long is it expected to run for?
December 2022 to August 2025

Who is funding the study?
Arrow Development S.L. (Spain)

Who is the main contact?
1. Dr Alberto Ortiz-Vigón, alberto@ortizvigon.com
2. Dr Erik Regidor, erik@ortizvigon.com

# Contact information

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# Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
PS2022090

# Study information

### Scientific Title
Analysis of passive fit through the use of photogrammetry for taking impressions of implants: a randomized clinical trial

### Study objectives
The use of the PIC Dental (photogrammetry) camera offers a greater passive fit than can be achieved with intraoral scanners on implant crowns.

### Ethics approval required
Ethics approval required

### Ethics approval(s)
Approved 08/03/2023, Comité ético de investigación clínica Euskadi (Basque clinical research committee) (C/ Donostia-San Sebastián, nº 1., Vitoria-Gasteiz, 01010, Spain; +34 (0)945 015 634; ceic.eeaa@euskadi.eus), ref: PS2022090

### Study design
Two-armed randomized controlled clinical trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Other

### Study type(s)
Treatment

### Participant information sheet
No participant information sheet available

### Health condition(s) or problem(s) studied
Patients with at least one implant awaiting impression-taking or registration to make and place their implant-supported crown

### Interventions

Randomization will be performed using a Microsoft Excel®-generated randomization list, with the treatment allocation contained in sealed envelopes that will be prepared by a research assistant not involved as clinician or examiner. Both the patient and the clinician performing the treatment will be masked to the group allocation until the randomization envelope will be opened during prosthetic treatment. The examiner will be masked to the group allocation at all follow-up visits, and the patients will be asked not to reveal their treatment assignment to the examiners.

Patients presenting at least one implant will participate in the study. After the integration period, periodontal maintenance will be performed and the researchers will take a periapical (2D) radiograph.

After this radiograph the healing abutment will be removed and the prosthetic abutment will be placed. Then, those participating in the test group will receive PIC transfers on their prosthetic abutments and registration will be performed with a PIC dental Camera. In the control group, scanbodies will be placed on their prosthetic abutments and registration will be performed with an intraoral scan.

After 10-15 days, implant-supported restoration or crown will be placed and a new periapical radiograph will be obtained. Then, 6 months and 12 months follow-up visits will be performed with clinical, radiographic and patients reported outcomes.

## Intervention Type
Procedure/Surgery

## Primary outcome measure
Passive adjustment or fit measured at the radiographic level. Measurements will be made using image analysis software (Image J. National Institutes of Health (NIH); Bethesda, MD, USA) calibrating the software through a known length, which could be the length of the implant. This is measured from the implant shoulder of the implant to the first bone-to-implant contact in both the mesial and the distal aspects in radiographs (two points per implant). Measured at baseline, 6 months and 12 months.

## Secondary outcome measures
1. Probing depth measured with a periodontal probe (UNC-15, Hu Friedy, Chicago, IL) at six points per implant at baseline, 6 months and 12 months
2. Bleeding on probing measured with a periodontal probe (UNC-15, Hu Friedy, Chicago, IL) at six points per implant at baseline, 6 months and 12 months
3. Time for taking impressions or registrations on implants during the prosthetic procedure, measured with a watch in minutes and seconds
4. Radiographic variables: radiographic bone loss measured from the shoulder of the implant to the first bone-implant contact in both mesial and distal aspects at two points per implant at baseline, 6 months and 12 months
5. Patient perception measured with a questionnaire and visual analogue score at baseline after the prosthetic procedure

## Overall study start date
01/12/2022

## Completion date
01/08/2025

# Eligibility

### Key inclusion criteria
Patients with implants placed in the clinics participating in the study who are awaiting impression taking or registration to make and place the implant-supported crown

### Participant type(s)
Patient

### Age group
Adult

### Sex
Both

### Target number of participants
48

### Key exclusion criteria
1. Patients with implants placed in other clinics whose prior treatment is unknown and may interfere with the objectives of the study
2. Implants with mobility whose indication will be their removal due to lack of integration
3. Implants that already have implant-supported crowns and there is an indication to repeat the crown due to fracture or loss of retention

### Date of first enrolment
01/01/2024

### Date of final enrolment
01/01/2025

# Locations

### Countries of recruitment
Spain

### Study participating centre
**Clínica Ortiz-Vigón & PerioCentrum Bilbao**
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# Sponsor information

### Organisation
Arrow Development SL

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### Sponsor type
Industry

## Funder(s)

### Funder type
Industry

### Funder Name
Arrow Development SL

## Results and Publications

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

### Intention to publish date
01/08/2026

### Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the results publication

### IPD sharing plan summary
Published as a supplement to the results publication

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Protocol file | | | 16/03/2023 | No | No |