**Title:**

Analysis of passive fit through the use of photogrammetry for taking impressions on implants. Randomized clinical trial.

**Key words:**

Dental implants, photogrammetry, intraoral scan, digital impressions.

**Background:**

Throughout the last decades, complete restorations on implants have become an increasingly safe and predictable procedure when it comes to replacing missing teeth or those with an impossible prognosis (1,2). New technologies adapted to the dental sector, including digital capture systems and surgical and prosthodontic planning software, have led to the digitization of work protocols in implant restorations.

A correct registration of the position and angulation of the implants is critical to achieve a passive adjustment in the structures that we place on implants, this being the key to long-term success in prosthetics on implants. Conventional or analog impression-taking methods have shown a reasonable and clinically acceptable discrepancy; however, they are procedures exposed to many factors that could alter the final result, and are also procedures that require numerous appointments for different tests, with considerable length and often unpleasant for patients (3).

As a digital alternative, the industry provided dentistry with intraoral scanners to make this type of registration. Intraoral scanners allow to reduce the errors that are introduced in a conventional way during the taking of delicate impressions and allow to increase the precision and adjustment of the structures, reduce the number and duration of appointments and overall treatment time, also being a more comfortable process. and satisfactory for patients (3). This type of digital solutions using intraoral scanners have shown great precision and fit, mainly in unitary and partial restorations on implants. In recent years, given the improvements that have been made to scanners both in software and hardware, their use for full-arch rehabilitations has been extended, due to the fact that they are reducing the margin of error or distortion. However,

they continue to be acquisition tools that depend on multiple factors, such as the number of implants, distance between them, operator experience, ambient light, mouth opening capacity, or anatomical location between the maxillary or mandibular area. And therefore, it is a procedure by itself not reproducible. One of the biggest challenges in this field and where there is still some uncertainty associated with the precision that it could achieve is in recording for full-arch rehabilitations. In addition, the presence of saliva, blood, or reflective restorations often complicate impression taking and increases the risk of error.

In parallel, as another digital alternative for implant records, a new system based on photogrammetry called Pic Dental® (Iditec North West SL) (4-8) began to be developed in 2010. This system is based on the use of a dual camera (Pic Camera®) that records the relative position of the Pic transfers® (three-dimensionally coded attachments) that are screwed onto the implants, thus providing the position and direction vectors of each one of them. at the same time that it relates them to each other, obtaining a precise measurement of the angles and distances between each one of the implants placed in the same arch. For a correct registration, it is described that the camera must be placed at a distance of 15-30cm from the patient's mouth and at an angle of no more than 45 degrees. In this way, the capture time may not exceed 20 seconds for each implant. In addition, during registration it allows the patient's mobility and details such as the presence of saliva bubbles or some bleeding, without interfering with impression taking. Consequently, it is a capture system that does not depend on the influential factors that determine precision, as is the case with intraoral scanners and which have been mentioned above. Another of the advantages attributed to it is that if the position of two implants is very close or they converge between them, it allows the capture to be made in several phases, unscrewing that Pic transfer® that is not the reference at that moment. After the capture, a PIC file or STL file is obtained that contains information on the exact position of the implants in the design and planning software (Pic Pro®). For the registration of the rest of the structures, such as soft tissues, it is necessary to obtain another STL file. Subsequently, these files are sent to the laboratory where they are superimposed using software such as Exocad® in a procedure called `Best-fit´. After the alignment of these files is when the structure is designed to be sent to the milling center (Pic Center®) and thus design the structure on implants.

**Objective:**

The overall objetive of the study is to evaluate the efficacy of both methods in achieving passive fit of implant-supported restorations or crowns.

**Main objective:** passive adjustment or fit measured at radiographic level. Measurements will be made using a image analysis software (Image J. National institutes of Health (NIH); Bethesda, MD. USA) calibrating the software through a known length, that could be 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 (2 points per implant).

**Secondary objectives/endpoints:**

To analyze the impact that the passive fit could have on the health of the implant by analyzing the following clinical variables:

- Probing depth: measured with a periodontal probe (UNC-15, Hu Friedy, Chicago, IL) at 6 points per implant
- Bleeding on probing: measured with a periodontal probe (UNC-15, Hu Friedy, Chicago, IL) at 6 points per implant
- Time for taking impressions or registrations on implants
- Radiographic variables:
  - Measurements of radiographic bone loss. This is measured from the shoulder of the implant to the first bone-implant contact in both, mesial and distal aspects. 2 points per implant.

**Rationale for the study:**

There is no enough evidence to evaluate the clinical efficacy of the PIC dental photogrammetry camera in obtaining a better passive fit in implant supported crowns when comparing with intraoral scanners.

**Hypothesis:**

The use of the PIC Dental camera offers a greater passive fit than can be achieved with intraoral scanners on implant crowns.

**Relevance for clinical practice:**

The results of this project will help to understand the use of this innovative

**Materials & Methods:**

**Study population, design and treatment procedures:**

The project will be conducted as a two-armed randomized controlled clinical trial of 1-year duration in 2 clinical centers. 40 systemically healthy patients with implants needing a prosthetic procedure to design their implant-supported crown.

**Inclusion criteria:**

Patients who meet the following inclusion criteria will be included:

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

**Exclusion criteria:**

Patients presenting at least one of the following exclusion criteria will be excluded:

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

**Prosthetic procedures:**

Patients presenting at least one implant will participate in the study. After integration period, a periodontal maintenance will be performed and we 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 test group, will receive PIC transfers on their prosthetic abutments and registration will be performed with PIC dental Camera. In the control group, scanbodies will be placed on their prosthetic abutments and registration will be performed with 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.

**Clinical assessments:**

Clinical assessments will be obtained during prosthetic procedure, and at 6 and 12 months re-examinations. Analysis of these clinical parameters will be performed by a specialist. The examiner will be blinded to treatment procedures.

**Radiographic assessments:**

Intra-oral radiographs will be obtained prior to prosthetic procedure (baseline) and at 6- and 12-months re-examinations. Analysis of radiographs will be performed by a specialist. The examiner will be blinded to treatment procedures.

**Indication:**

Patients with at least 1 implant needing a prosthetic procedure to registration or impressions to design and placement of their implant-supported crown.

**Power calculation:**

According to Syrek 2010 and Derksen 2021, a difference of 20 microns in the marginal gap with digital impressions (Standard deviation 15microns), in comparison with conventional impressions. This difference would have clinical relevance, so with a power of 0.90 and a level of probability of 0.05, we should need at least 48 patients, being 24 per group.

**Data analysis:**

The statistical analysis will take into account all the data collected before, during and after the surgical intervention. A descriptive statistic of the data obtained in both groups will be carried out during the study. For the analytical statistics a Shapiro-Wilk normality test will be performed for the quantitative variables. The changes in the means obtained between the initial situation and 12 months of follow-up will be evaluated using a McNemar test. The patient is the unit of analysis. The data obtained will be analyzed through the SPSS SPSS Statistics Desktop program, V21.00 (SPSS Inc., Chicago, IL, USA

**Schedule of investigational events:**

The flow chart and time schedule presented below illustrate the overall organization of the study including the sequence of examinations:

1. Ethical approval of protocol by local ethics committee
2. Study announcement and patient recruitment
3. Screening and identification of subjects. It is estimated that it will take about 18 months to recruit the total number of patients required for the trial

4. Baseline clinical examination of implants selected for the study. Periodontal maintenance. Photographs, data collection of clinical parameters and measurements.

5. Radiographic examination.

6. Prosthetic procedure with PIC Dental camera (test) or intraoral scan (control). Patient reported outcomes questionnaire.

7. 2 weeks: implant-supported crown placement

8. 24 weeks: photographs, periapical radiography, clinical assessment.

9. 48 weeks: photographs, periapical radiography, clinical assessment.

**Ethical considerations and institutional review:**

The protocol is being reviewed by the local Ethics Committee of Basque Country and the study will be registered at isrctn.com.
Each patient will receive oral and written information about study purpose and design and they will have to sign a consent. Patients have to understand that their participation in the study is voluntary and they can leave it when they want. The study will be carried out following the recommendations of Helsinki declaration. All the included patients will receive the prosthetic restoration of their implants and any adverse reaction will be recorded during the follow-up visits.

**1. Facilities and expertise:**

**Study team:**

***Principal investigator:***

Alberto Ortiz-Vigón (Department of Periodontology, Periocentrum Bilbao) has extensive experience in the field of periodontology, implant dentistry and peri-implantitis clinical research

***Study monitoring:***

Erik Regidor (Department of Periodontology, Periocentrum Bilbao) has experience in monitoring randomized controlled clinical trials. He will attend all the study during the inclusion period as well as the follow-up period.

***Clinical / practical work:***

All investigators are trained researches and specialists in periodontics & prosthodontics.
All of them have an extended experience in periodontology, implant dentistry and restoration

**2. Organization:**

The study will be organized and monitored from Periocentrum Bilbao:

Principal Investigator: Dr. Alberto Ortiz-Vigón (Periocentrum Bilbao, Bilbao, Spain)
Clinical Research Coordinator: Dr. Erik Regidor (Periocentrum Bilbao, Bilbao, Spain)

**3. Infrastructure**

Periocentrum Bilbao has extended experience in periodontology and clinical research.
Periocentrum Bilbao will be responsible of their data collection and when the study is finished, data analysis and interpretation will be made.

**4. Economy**

Periocentrum Bilbao will be responsible for the cost of the surgical treatment of each included patient and follow-up visits until the protocol is completed

## 5. References


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