Application Report to the Biomedical Research Ethics Committee.

Title: Conventional versus digital impressions. Which offers a better quality of life?

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Abstract:

Taking impressions or records of oral structures is one of the most common procedures in daily dental practice. It is used for a wide variety of treatments: study models, prosthetic procedures, occlusal splints, etc. Traditionally, these impressions have been made using alginate and silicone of different consistencies, as well as other biomaterials. These types of materials require a setting time, starting out viscous and then solidifying in the patient's mouth, leaving us with a negative reproduction of the dentition and surrounding structures. At times, this process could be uncomfortable for the patient due to the occurrence of nausea, a sensation of shortness of breath or choking, and even vomiting during their use. Alongside advances in biomaterials, technological advances have introduced digital impression-taking through the use of scanners in which an intraoral camera is used to capture thousands of images per second as it moves around the mouth, allowing the computer to reconstruct a three-dimensional model of the patient's mouth. The aim of this study is to evaluate which of the two methods, analogue/traditional or digital, is more comfortable for the patient and the dentist.

15 de diciembre 2023

Introduction and Background:

Traditionally, impressions have been used as a means of replicating the patient's mouth on a workbench, enabling laboratory technicians to manufacture prosthetic devices without the patient needing to be present. Almost all cases require an average of two impressions, the first being a study model so that the dentist can plan the treatment and make any necessary changes before work is carried out on the patient. The second impression is taken when definitive work on the patient begins.

The conventional impression-taking method involves the use of alginate and silicones. The material is placed in a tray that is inserted into the patient's mouth and pressed against the teeth; it is then held still until setting is complete, resulting in a negative reproduction of the dentition and surrounding structures. Currently, this process is the most widely used and the most cost-effective; however, it may be uncomfortable for the patient.

In recent years, alternatives to the traditional method have been developed in an attempt to achieve greater accuracy and a better workflow. Intraoral scanners were introduced in the 1980s; as technological advances occurred, these intraoral scanners became faster and more accurate with the incorporation of artificial intelligence. Currently, intraoral scanners available on the market allow an average scanning time of 75 seconds per arch in the standard-resolution setting, and also intelligently identify objects in the images being captured, such as the tongue, molars, premolars, metal crowns, etc. They also offer the possibility of subsequently omitting certain parts of the captured images to reduce file size. With this technology available, the dentist can offer the patient a more satisfactory treatment experience.

Objectives:

Primary:

- To determine which impression method patients, prefer: a traditional impression or a digital impression using an intraoral scanner.

Secondary:

- To validate the questionnaire used.
- To evaluate, at the clinical level, which procedure has a faster and smoother workflow.

Methodology:

Study type: observational study.

Sample size: 112.

Inclusion criteria:

- Patients over 18 years of age.
- Patients who require impressions for clinical study and/or prosthetic work.

Exclusion criteria:

- Patients with allergies to the materials used.
- Patients with epilepsy.
- Edentulous patients.

Study subjects will be from the patients of the master's degree in Oral Surgery and Oral and Facial Implantology at the University Dental Clinic of CEU Cardenal Herrera University in Valencia, who will be undergoing treatment in the department and getting the impressions taken as part of the standard protocol of the department. Participants willing to participate will have to meet the established inclusion and exclusion criteria.

A crossover observational study is established to determine which impression method the patient prefers: the use of the traditional impression method or the use of an intraoral scanner. Both techniques will be applied to each patient in the maxilla. The technique used first will be following an alternating order. The patient will be asked to complete a questionnaire following the application of each procedure (Annex 1).

Variables:

- Pain level.
- Discomfort from temperature.
- Discomfort from pressure.
- Discomfort from nausea.
- Satisfaction from duration.
- Willingness to repeat.
- Level of satisfaction.

Statistical Analysis:

Data analysis will be performed using Python 3.13.5, with NumPy 2.3.5, SciPy 1.17.0, and statsmodels 0.14.6. Descriptive statistics will be calculated for all variables. Continuous variables will be presented as means and standard deviations. Comparisons between digital and conventional impression techniques will be performed using paired Student's t-tests, with statistical significance set at $p < 0.05$.

Scientific and Ethical Justification:

The present study will be conducted in accordance with the Declaration of Helsinki concerning medical research. Following ethical approval by the Ethics Committee of CEU Cardenal Herrera University, data will be collected from patients of the Master's Degree in Oral Surgery and Oral and Facial Implantology at the University Clinic of CEU Cardenal Herrera University who meet the established selection criteria.

All participants will be informed of the purpose, protocols, and procedures. They will be informed that they may withdraw from the study at any time and without prior notice, without this affecting the subsequent treatment and care provided by clinicians. Additionally, they will be informed that they may contact one of the dentists at any time to ask any questions about the research or regarding issues related to postoperative complications and unexpected events. Patient participation will be confidential, as will all personal data used, and each patient will have access to the records generated throughout the study. Participants' privacy and the protection of their data will be

safeguarded in accordance with Organic Law 15/1999 of December 13 on the Protection of Personal Data. This study will comply with the ethical principles for medical research involving human subjects established in the World Medical Association's Declaration of Helsinki. Data will only be processed confidentially by the researchers. All data will be entered into a OneDrive account to which only the principal investigator and the doctoral candidate will have access. Once the study is completed, all data will be destroyed.

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CONSENT DOCUMENT FOR PARTICIPATION IN A RESEARCH PROJECT

PROJECT TITLE: Conventional versus digital impressions. Which offers a better quality of life?
PRINCIPAL INVESTIGATOR: Dr. Isidoro Cortell Ballester

Mr./Ms. _____
With National Identity Document (DNI) No. _____
Freely and voluntarily

I DECLARE:

1. I have read and understood the study information sheet.
2. I have had the opportunity to ask questions.
3. My questions have been answered satisfactorily.
4. I have received sufficient information about the study and the tests to be performed.
5. I understand that participation is voluntary and that I may withdraw from the study whenever I wish without having to provide explanations and without this affecting my medical care.
6. In accordance with Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC, I have been informed that my personal data, obtained by completing this form as well as those resulting from my participation in the project, will be processed under the responsibility of FUNDACIÓN UNIVERSITARIA SAN PABLO CEU (hereinafter, FUSP-CEU), for the purpose of managing my participation in this research project. In addition, I have been informed of the following aspects:
    a. That profiling is planned for the purpose of analyzing or predicting aspects related to my health.
    b. That the indicated processing activities are legitimized by the consent I have given.
    c. That my personal data, obtained by completing this form, as well as those resulting from my participation in the project, will be retained for the period

necessary for the development of this research, estimated at 12 months, and subsequently destroyed, and may not be retained unless they have first been anonymized. In any event, they may not be transferred without my express consent, which I do not grant hereby.

d. That I may contact the Data Protection Officer of FUSP-CEU by sending my request in writing to the postal address C/ Tutor No. 35 - 28008 Madrid or to the email address dpd@ceu.es.dpd@ceu.es

e. That, in accordance with the rights granted to me by current data protection regulations, I may contact the competent Supervisory Authority to lodge any complaint I consider appropriate, and may also exercise the rights of access, rectification, restriction of processing, erasure, portability and objection to the processing of my personal data and withdraw the consent given for their processing by addressing my request to the responsible investigator at the contact address indicated in this document.

7. I agree that my written consent and other data may be made available to the clinical research project in which I am participating and to the investigator responsible for it, Dr. Isidoro Cortell Ballester, while always respecting confidentiality and ensuring that my data will not be publicly available in a way that would allow me to be identified.

8. The data collected for this study will be included, together with those of other persons participating in this study, in a personal data database of CEU Cardenal Herrera University, to which only the researchers approved for this project will have access, all of whom are subject to the duty of confidentiality inherent in their profession or arising from a confidentiality agreement.

9. I voluntarily sign this information and consent document to express my wish to participate in this research study on “Conventional versus digital impressions. Which offers a better quality of life?”, until I decide otherwise. By signing this consent I do not waive any of my rights. I will receive a copy of this document to keep and consult in the future.

Therefore, I give my agreement and consent for the detailed study to be carried out with the assistance of any necessary personnel with the appropriate qualifications and specialization.

The participant
(Signature) First name, Surname(s)

Valencia, on the …… day of …… of ……

AUTHORIZATION BY FAMILY MEMBER OR GUARDIAN

Given the inability of Mr./Ms. _____

with DNI _____ to give authorization for the treatments specified in this document freely, voluntarily and consciously.

Mr./Ms. _____

with DNI _____

In my capacity as (husband, wife, son/daughter, brother/sister, legal guardian, family member, close associate, caregiver), I decide, from among the available clinical options, to give my free, voluntary and conscious agreement to the technique described for the treatments specified in this document.

_____, _____ of _____ of _____

INVESTIGATOR

Mr./Ms. _____

with DNI _____

Email address:

Telephone:

As a researcher at CEU Cardenal Herrera University in Valencia, I declare that I have provided the study participant and/or authorized person with all the information necessary to carry out the intervention specified in this document, and I declare that I have confirmed, immediately before applying the technique, that the participant does not fall within any of the cases of contraindication mentioned above, and that I have taken all necessary precautions for the intervention to be performed correctly.

_____, _____ of _____ of _____

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REVOCATION OF INFORMED CONSENT

Mr./Ms. _____

with DNI _____

I revoke the consent granted on the _____ day of _____ of _____

And I do not wish to continue the treatment, which I hereby consider terminated as of this date.

_____, _____ of _____ of _____