Clinical evaluation of the effect of the scanning pattern on complete-arch implant scans (strategies IOS)

C.I. 22/645-E

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Study protocol and Statistical Analysis Plan

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INTRODUCTION AND BACKGROUND

Record-taking is a fundamental process and the starting point for manufacturing a dental prosthesis. The appearance of intraoral scanners (IntraOral Scanners (IOS)) has meant a revolution in this regard due to the advantages they provide, including better communication with both the patient and the dental laboratory, better comfort and acceptance by the patient, the immediacy in sending the file and saving space in the storage of digital models versus conventional ones. However, they are not exempt from problems, including their high cost, the learning curve, and difficulty achieving a reliable record in certain circumstances, including edentulous full-arch records.

Recordings of the edentulous full arch with IOSs pose a challenge due to the type of operation of these devices, which gradually collect and overlap information from small areas until completing a full arch. For this reason, different techniques have been proposed to improve the accuracy of this type of recording. In addition, if there is a case in which accuracy is crucial, it is complete edentulous arches with implants since, if the registration is not exact, the prosthesis manufactured on it will not have a passive fit in the mouth, which would lead to the appearance of both biological and mechanical complications.

Different studies have tried to analyze how various factors influence this accuracy, and these factors can be divided into factors related to the operator, the scanner, environmental conditions, or intraoral conditions—also different scanning strategies or heights and positions of the scan bodies. However, most of these works have been developed in an in

vitro environment. This fact is motivated by the greater ease of making the records and, as a more relevant fact, the possibility of obtaining a reliable reference model, employing a coordinate machine (Coordinate Measurement Machine (CMM)) or a desktop scanner, something that in an in vivo study it is not possible.

The present study aims to clinically analyze the accuracy of different intraoral scanning strategies and types of scan bodies in edentulous full arch registrations on implants.

JUSTIFICATION

Due to the importance of the accuracy in taking digital impressions in full-arch patients for the fabrication of restorations on implants, it is considered justified to study the influence of different scanning strategies and scan bodies on the accuracy of full-arch recording.

VIABILITY

The project could be considered viable by having all the instruments and apparatus necessary to develop the material and methods. It is estimated that the proposed methodology could be developed within the period described.

AIM

The purpose of this in vivo study will be to measure the influence of different scanning strategies (zigzag with conventional scan body, circumferential with conventional scan body, surface blocking with conventional scan body, zigzag with low profile scan body, standard strategy with low profile scan body) on the accuracy of the records obtained for a case of fixed rehabilitation on full-arch dental implants.

HYPOTHESIS

The null hypothesis will be that there are no significant differences in scanning accuracy (trueness and precision) between the different groups of digital impressions compared to the reference model (conventional impression with rigid splinting).

The alternative hypothesis will be that there are significant differences in scanning accuracy (trueness and precision) between the different groups of digital impressions compared to the reference model (conventional impression with rigid splinting).

MATERIAL AND METHOD

A patient will be selected who is susceptible to rehabilitation with a fixed prosthesis on implants, in good general health (ASA I and ASA II), without joint problems or limitation of opening, and who, after reading the information sheet, the patient and informed consent, and clarified any doubts, voluntarily agree to participate in the study.

A reference model will be taken with a high-precision conventional methodology such as Rigid Impression Splinting. A first impression will be taken with double-mix addition silicone (putty and fluid) with an open tray. From this record, a first model will be generated that will be used to splint the impression transfers with a rigid, low-shrinkage light-curing material, which will later be sectioned with discs. Subsequently, the transfers will be screwed with the splint in the mouth and rejoined using a low-shrinkage light-curing material, thus minimizing the possibility of accumulation of errors. A second impression will be taken dragging the entire set, and it will be cast in improved type IV plaster (GC Fujirock; GC), thus obtaining the master model. This model will be digitized using a laboratory scanner to get the reference digital model, against which the specimens resulting from the experimental groups will be compared.

Six experimental groups will be created based on the strategy-scan body used (1.- zigzag with conventional scan body (ZZ-SBL), 2.- circumferential with conventional scan body (C-SBL), 3.- surface blocking with scan conventional body (B-SBL), 4.- zigzag with low profile scan body (ZZ-SBL), 5.- a standard strategy with low profile scan body (STD-SBL), 6.- single pass with low profile scan body (OP-SBL) These experimental groups

will be scanned directly in the patient's mouth, to be compared with the reference model, called the "master model".

Based on previous studies, a sample size of n=15 is estimated for each group. A pilot study will be carried out with n=5, from which a statistical test (G* Power; University of Düsseldorf) will be carried out to calculate the sample size. All digitization procedures will be performed under lighting conditions of 1000 lux measured with a lux meter (LX1330B Light Meter; Dr. Meter Digital Illuminance) and at a constant temperature of 24 +/-2 ºC. Once the files are obtained, they will be exported with the reference format for a 3-dimensional.STL (standard tessellation language) file to a metrology program (Geomagic Control X). The results will be compared with a reference file, and the deviations of the implant positions will be obtained using the best-fit algorithm. The mean square error (Root Mean Square) will be calculated.

statistical plan

Statistical tests will be developed to check the normal distribution of the samples, Shapiro-Wilk or Kolmogorov-Smirnov type. A priori tests will be carried out to verify the existence of statistically significant differences, and a posteriori for analyzing which groups such differences appear and their magnitude. Statistical power will be 95%, so those with $p<.05$ will be considered statistically significant differences. All statistical analysis will be performed using a statistical software program (IBM SPSS Statistics for Windows, v26; IBM Corp).

VARIABLES COLLECTED AND DESCRIPTION OF THE ACTIONS TO BE CARRIED OUT AND FINAL DESTINATION OF THE SAMPLES

The collected variable is the discrepancy in the position of the implants between the control model, reference, and the experimental groups, quantified as a Root Mean Square. The samples, in this case, files, will be saved anonymously on a hard drive, named so that

the group to which they belong and the number of samples can be interpreted (Example: ZZ-SBL1). The scanning time and the number of frames will also be collected.

SCHEDULE

December 2022-March 2023: collection, sample preparation, development of experimental methodology, and data collection.

April 2023-July 2023: Statistical analysis and writing of the manuscript.

ETHICAL IMPLICATIONS

To the best of the research team's knowledge, the most significant ethical implication lies in carrying out several recordings of the same patient. In this regard, it should be noted that, in addition to meeting the inclusion requirements, the participant wishes to participate completely voluntarily and know that the participant will not obtain any compensation, financial or in any other way. On the other hand, we must bear in mind that intraoral record-taking procedures with intraoral scanners can be considered harmless and painless, which simply means that the patient must keep his mouth open during the procedure.