Customized Impressions in Dental Implants - Soft Tissues Changes

NCT03496428

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Study Protocol with Statistical Analysis Plan

2.1 | Patient selection

This clinical study was conducted in full compliance with the Helsinki World Medical Association Declaration and its most recent amendments, being approved by the local ethics committee and registered at the U.S. National Library of Medicine ClinicalTrials.gov website under the reference number NCT03496428.

The patients were chosen according to the following criteria: be at least 18 years of age; have at least one implant in the anterior maxilla with the indication for rehabilitation with a definitive implant supported crown; have two mesial and two distal adjacent teeth to the implant and be rehabilitated with a provisional implant supported crown for at least 3 months. As this was a pragmatic trial undertaken in a private clinical setting, patients with active smoking habits and evidence of parafunctional habits (ie, bruxism) were not excluded. Each patient was thoroughly informed about the procedures and each signed an informed consent agreement before entering the study.

2.2 | Digital impression method

Following the digital workflow method above (Figure 1), immediately after the removal of the provisional implant supported crown, digital impressions were the first to be obtained by an experienced clinician (DM) using an IOS (TRIOS, 3Shape, Copenhagen, Denmark) following the manufacturer recommended scanning sequence—first, the emergence profile was scanned right after the removal of the provisional crown (Figure 2A) to assess the emergence profile, after which a scan body was attached to the implant and an intraoral scan performed (Figure 2B,C) to obtain the implant analogue alignment (Figure 2D). This IOS uses optical scanning with structured light on the principle of confocal microscopy, which does not require opacization of the model and produces 3D color images. The datasets from each scan were automatically saved as STL files.

2.3 | Conventional impression method with coping customization, stone model fabrication,

and digitalization

In the same appointment, following the conventional workflow method (Figure 1), the CIIC was obtained by a previously described indirect technique. Briefly, the provisional crown was attached to an implant analog and placed into a polyvinyl siloxane impression material matrix (Affinis Putty, Coltene, Altstätten, Switzerland). The mold was obtained and the provisional returned to the patient's mouth to avoid soft tissue collapse. The impression coping was attached to the implant analog and filled with composite resin (Supreme 3M flow, 3M ESPE, Saint Paul, Minnesota), which took the 3D shape of the provisional soft tissue emergence, thus obtaining a CIIC (Figure 3). It was hand tightened and the proper seating was confirmed by visual and X-ray verification.

A dual viscosity impression in one-step pick-up procedure was constructed using a polyvinyl siloxane material (Affinis Light Body Type 3, Putty soft Type 0, Coltene, Altstätten, Switzerland) in a standard plastic die lock tray (Single Use Perforated Impression Tray, Solo, J&S Davis, Stevenage, Herts, United Kingdom) prepared prior to loading into position. The impression was removed from the patient's mouth at least 2 minutes longer than the manufacturer's recommendation (2 minutes) and stored at 23ºC for 8 hours. The impression was poured with type IV dental stone (Top Super Hard Stone, class IV light yellow, Sherahard-rock, SHERA

Werkstoff-Technologie GmbH & Co. KG, Lemförde, Germany) after mixing according to manufacturer instructions. The stone model was separated from the impression after 40 minutes, stored at laboratory temperature (21ªC-23ªC) for 24 hours with no exposure to sunlight, and then scanned with the extraoral scanner D2000 (3Shape, Copenhagen, Denmark) with 5-megapixel high resolution cameras, multiline technology, and color scanning, achieving accuracy up to 5 µm, thus creating a STL file, which was previously calibrated according to manufacturer's instructions. This digitalized model was considered the reference.

2.4 | 3D analysis

Two STL files were obtained from each patient and, to allow for blinding, an external operator provided the STL files named with the patient reference number followed by the letter A (reference) or B (measured), keeping the correspondence code in an opaque sealed envelope until the end of the study. The files were imported into a reverse engineering software Geomagic Design X (3D Systems, Rock Hill, South Carolina) where they were cut to the zone of interest with the “Split” tool, removing unnecessary information and submitted to the “Healing Wizard” to reduce the number of distortions and small artifacts that could influence analysis. The generated datasets were then imported into the point-cloud inspection software Geomagic Control X (3D Systems).

Software validation was performed as previously reported and repeated five times per scan (60 repetitions in total) to check software reliability, after which, virtual sagittal planes were created to guide the standardization of the locations of interest—through the cervicalapical axis of each of the five structures (four teeth and one implant), frontal planes over the mesiodistal axis of the implant and the two adjacent teeth, three transversal planes parallel between them in the four teeth, one at the gingival zenith and two others apically from the first with 1 mm spacing between them, and in the implant at emergence profile base level which was defined with a horizontal plane in the most apical identifiable point of the customized emergence profile, mucosal zenith, and in the middle of them. The locations were determined by the intersection between the described planes with the superimposed scans and the linear differences obtained by the 3D analysis program. The amount of deviation between methods was obtained by calculating the root mean square (RMS) by previously established methods.

To evaluate the trueness between conventional (reference) and digital (comparison) impression methods, RMS distances were determined on both the buccal and palatal sides of the teeth, at cervical, incisal and in the middle point between them in each tooth (Bc, Bm, Bi, Pc, Pm, and Pi) and in the respective soft tissues (Gbc, Gbm, Gbz, Gpz, Gpm, and Gpc), as shown in Figure 4A. In the interproximal area of the implant (mesial and distal sides, Mip and Dip), the same locations as in buccal/palatal were measured (Figure 4B). In total, 304 comparisons were performed in teeth's hard and soft tissues to assess trueness between methods.

To evaluate the soft tissue replication between methods in periimplant soft tissues, the locations were measured at emergence profile base level (epbl), at the zenith (z), and middle (m) on the different sides of the implant mucosa: the buccal of the buccal mucosa (Bbm), the palatine of the buccal mucosa (Pbm), the buccal of the palatine mucosa (Bpm), the palatine of the palatine mucosa (Ppm), and the mesial and distal mucosa (Mm and Dm, respectively) (Figure 4C,D), corresponding to 18 locations per patient, amounting to a total of 108

measurements. If the scans presented teeth with modifications, for prosthesis fabrication or distortions, the affected areas were not assessed.

For each location with the “3D Compare” tool an area of interest with at least 1 mm2 was selected and used to measure the differences between methods, with three replicates performed per location. The analysis software automatically calculated RMS and the mean of the three replicates considered for statistical analysis.

For optimal 3D visualization, a colored map was created with negative (blue, showing the comparison scan going inwards) and positive values (red, going outwards), as shown in Figure 5. Specific parameters were set to the color scale, ranging from +1000 to −1000 µm and the best results ranging between +100 and −100 µm, highlighted in green. Values over or below the color scale's limits were presented in gray.

2.5 | Statistical analysis

Although no studies employing this technique were found in the literature, from a study on direct and indirect techniques in CIIC22 we expected a mean difference of 1 mm. A statistical power analysis was performed to determine the number of patients with an equivalence study design. With an $\alpha = .05$, and a power of 0.80, the calculations revealed that at least six patients would be needed to be 95% sure that the limits of a two-sided 90% confidence interval would exclude a difference in means of more than 500 µm.

Primary outcomes were defined as the variation in the RMS between the two methods in the hard (teeth) and soft (teeth and periimplant mucosa) tissues' measurements. Descriptive statistic (means and 95% confidence intervals) was performed on the studied parameters. Normality of distribution was tested by the Shapiro-Wilk Normality test and the Levene test was used to assess the equality of variance. According to the results, the nonparametric Mann-Whitney U and Kruskal-Wallis tests were used to compare RMS between methods in hard and soft tissues ($\alpha = .05$). When performing multiple comparisons, the P-value was adjusted according to the Bonferroni Correction method.

Effect size between soft tissues' measurements (tooth vs implants) was calculated as Hedges' g ± 95% confidence interval as a result of different sample sizes.27–30 Effect size was considered as small (<0.3), moderate (0.3-0.8), or large (≥0.8) effect. The level of significance was set at .05. All calculations were carried out with statistical software (SPSS 25.0, SPSS Inc., Chicago, Illinois).