STUDY PROTOCOL

Evaluation of Digital Impression Workflows for Cement-Retained Implant Abutments:A Methodological Clinical Study NCT Number:

Prepared by:
Ezgi Ünal, DDS, Specialist in Prosthodontics
Hacettepe University Faculty of Dentistry, Department of Prosthodontics

Supervisor:
Prof. Dr. Kıvanç Akça
Hacettepe University Faculty of Dentistry, Department of Prosthodontics

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Introduction

Advancements in digital technologies have significantly transformed diagnostic, planning, and treatment processes in dentistry. Digital workflows have redefined the procedures for impression-taking, design, and fabrication, offering enhanced predictability and clinical efficiency in prosthodontic treatments. Intraoral scanners (IOS), which acquire direct data from the oral cavity, have become central to this transformation by minimizing material- and operator-related errors commonly encountered in analog impression workflows.

In implant-supported fixed prosthodontics, the accurate and repeatable digital transfer of the three-dimensional (3D) implant position is critical for clinical success.(1, 2) Digital workflows typically rely on scan bodies (SBs), which serve as intermediaries between the implant and the digital design software. (2)However, in clinical scenarios where the implant brand is unknown or digital libraries are unavailable, using prefabricated cement-retained abutments as direct scanning references may be a necessary alternative.

While multiple in vitro studies have examined the accuracy of various scan body designs and materials, clinical-level evidence comparing different digital workflows for scanning cement-retained abutments is still limited.(3) Moreover, methodological variables such as library dependency and software alignment algorithms may affect measurement accuracy.(4)

In recent literature, direct intraoral scanning has been shown to offer improved efficiency and potentially better accuracy compared to indirect methods. (5, 6)Yet, the impact of scanning and alignment strategies on the clinical accuracy of digital impressions taken at the abutment level remains underexplored. Quantitative assessment of angular deviations between virtual implant axes using reverse engineering software provides an objective means to evaluate such workflows in clinical settings.(7, 8)

Objective

This clinical methodological study aims to evaluate the precision of intraoral scanning workflows used for the digitalization of cement-retained implant abutments. Three digital impression workflows were evaluated by comparing the angular deviations between the virtual axes representing implant positions, derived from scan body and abutment scan data.

The null hypothesis of the study is that there is no statistically significant angular deviation between the datasets obtained from intraoral and extraoral scanning of the abutments, aligned via the best-fit alignment protocol, and those obtained from intraoral scanning alone.

Study Design

This prospective clinical methodological study was designed in accordance with the STARD (Standards for Reporting Diagnostic Accuracy Studies) guidelines to assess the

precision of digital impression workflows for cement-retained implant abutments. The study was conducted at the Department of Prosthodontics, Hacettepe University Faculty of Dentistry, and approved by the university's Ethics Committee (Protocol No: KA-24057).

Twelve participants requiring two implant-supported fixed restorations in the posterior region were enrolled. All participants were adults with completed skeletal growth, and had no systemic or local contraindications for implant treatment. Bone-level implants (Straumann) were placed in accordance with the SAC classification as "straightforward" cases.

Three different digital workflows were applied to each participant in a single clinical session:

1. **SB (Scan Body Group):** Intraoral scan of original scan bodies screwed onto implants.
2. **IOS (Intraoral Scan Group):** Direct intraoral scan of prefabricated cement-retained abutments.
3. **BFA (Best-Fit Alignment Group):** Superimposition of intraoral and extraoral scan data of the abutments using best-fit alignment protocol.

Reverse engineering software was used to analyze angular deviations between the virtual axes derived from each workflow.

Eligibility Criteria

Inclusion Criteria:

- Adult participants aged 18 years or older who have completed skeletal growth.
- Signed informed consent after being informed about the study procedures.
- Good general and oral health, with no signs of active periodontal disease.
- Partially edentulous in the posterior region with indication for a two-implant-supported fixed dental prosthesis (2–3 units).
- Presence of fixed dentition in the opposing arch.
- No need for vertical or horizontal prosthetic correction of the interarch relationship.
- Presence of bone-level implants placed via straightforward surgery according to the SAC classification system, without any advanced surgical techniques.

Exclusion Criteria:

- Refusal to participate or failure to sign the informed consent form.
- Conditions contraindicating implant therapy (e.g., history of radiation therapy in the head and neck region, bone malignancies, severe metabolic disorders).
- Systemic risk factors for implant therapy (e.g., uncontrolled diabetes, immunological disorders, chronic steroid use, pregnancy).
- Local risk factors for implant therapy (e.g., bruxism, poor oral hygiene, untreated periodontal disease).

- Presence of temporomandibular joint disorders affecting mandibular movements.

Interventions

InterventionType: Other
Name: Evaluation of three digital impression workflows for cement-retained implant abutments

Description:
Each participant underwent three different digital impression workflows for the digitalization of cement-retained implant abutments in a single clinical session:

1. **SB (Scan Body Group):** Intraoral scanning of original scan bodies (CARES Mono Scanbody; Straumann Holding AG) attached to the implants.
2. **IOS (Intraoral Scan Group):** Direct intraoral scanning of prefabricated cement-retained abutments (Bone Level RC/NC Cementable Abutment; Straumann Holding AG).
3. **BFA (Best-Fit Alignment Group):** Best-fit alignment of intraoral and extraoral scan data of the same prefabricated abutments. Extraoral scanning was performed by attaching the abutments to implant analogs using a positioning holder and scanning them on a stable platform.

All impressions were acquired using an intraoral scanner (TRIOS 5; 3Shape A/S) with image stitching algorithm. Reverse engineering software (Geomagic Design X; 3D Systems Inc.) was used to calculate angular deviations between the virtual axes derived from each workflow.

Primary Outcome Measures

Outcome Name:
Mean angular deviation between digital workflows

Description:
The primary outcome is the comparison of mean angular deviations between the virtual axes derived from three different digital impression workflows used for the digitalization of cement-retained implant abutments. Reverse engineering software (Geomagic Design X; 3D Systems Inc.) was used to calculate angular differences between the datasets. The scanbody-based intraoral scan (SB group) was defined as the reference dataset for alignment and deviation analysis.

Time Frame:
Following the completion of all digital impressions and their alignment in the reverse engineering software.

Data Collection and Analysis

Intraoral scans were performed using a wireless scanner (TRIOS 5; 3Shape A/S, Copenhagen, Denmark) with confocal microscopy technology. All scans were conducted in a controlled clinical environment, and surface data were saved in Standard Tessellation Language (STL) format.

Three different digital workflows were performed on each participant in a single session:

- **SB Group**: Scan bodies (CARES Mono Scanbody; Straumann Holding AG) were screwed onto the implants and scanned intraorally.
- **IOS Group**: Prefabricated cement-retained abutments (RC/NC Cementable Abutment; Straumann Holding AG) were screwed intraorally and scanned directly.
- **BFA Group**: Extraoral scans of the abutments were obtained by combining them with implant analogs. These scans were later aligned with intraoral scans using a best-fit alignment protocol in CAD software (exocad DentalCAD; exocad GmbH).

The datasets were processed and analyzed using reverse engineering software (Geomagic Design X, version 2016.1.0; 3D Systems Inc., Rock Hill, SC, USA). For each group, the 3D positions of the implants were represented by central axes generated from cylindrical or conical geometries of the scanned components.

Statistical Analysis

Statistical analysis was performed using IBM SPSS Statistics 26.0. For each digital workflow (SB, IOS, BFA), the mean and standard deviation of angular deviations measured at different implant positions (mesial/distal) and arch locations (maxilla/mandible) were calculated.

The normality of the data distribution was assessed based on skewness and kurtosis values, with a reference range of ±1.96. As the data met the assumption of normal distribution, repeated measures ANOVA was used to evaluate differences between workflows with respect to jaw location and implant position. To identify which specific workflows differed significantly from each other, pairwise comparisons were conducted using the Least Significant Difference (LSD) test.

Additionally, to compare the performance of each workflow between the maxillary and mandibular regions, independent samples t-tests were performed. A significance level of $p<0.05$ was set for all statistical tests. Results were reported as mean ± standard deviation (mean ± SD), and findings were presented both in tables and visualized using heat maps and radar charts. This analysis allowed for the statistical comparison of the accuracy and consistency of each digital workflow across different implant positions.

1. Ferro KJM, S.M. ; Driscoll, C.F. ; Freilich M.A.; Guckes, A.D., Knoernschild K.L., McGarry, T.J. The Glossary of Prosthodontic Terms: Ninth Edition. J Prosthet Dent. 2017;117(5s):e1-e105.

2. Demir F. Evaluation of the Accuracy of Different Scan Posts Used for Direct Digital Impression in Implant-Supported Prosthesis Fabrication: A Methodological Clinical Study. Ankara, Turkey: Hacettepe University; 2022.
3. Mizumoto RM, Yilmaz B. Intraoral scan bodies in implant dentistry: A systematic review. The Journal of prosthetic dentistry. 2018;120(3):343-52.
4. Rutkūnas V, Gečiauskaitė A, Jegelevičius D, Vaitiekūnas M. Accuracy of digital implant impressions with intraoral scanners. A systematic review. Eur J Oral Implantol. 2017;10(Suppl 1):101-20.
5. Ahrberg D, Lauer HC, Ahrberg M, Weigl P. Evaluation of fit and efficiency of CAD/CAM fabricated all-ceramic restorations based on direct and indirect digitalization: a double-blinded, randomized clinical trial. Clinical oral investigations. 2016;20(2):291-300.
6. Güth J-F, Keul C, Stimmelmayr M, Beuer F, Edelhoff D. Accuracy of digital models obtained by direct and indirect data capturing. Clinical oral investigations. 2013;17(4):1201-8.
7. Ender A, Mehl A. Accuracy of complete-arch dental impressions: a new method of measuring trueness and precision. The Journal of prosthetic dentistry. 2013;109(2):121-8.
8. Ender A, Mehl A. In-vitro evaluation of the accuracy of conventional and digital methods of obtaining full-arch dental impressions. Quintessence international. 2015;46(1).