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Precision of Different Scanbodies Used for Direct Digital Impression in Fabrication of Implant Supported Fixed Prosthesis: A Methodologic Clinical Study.

Study Protokol: The study design was planned to comply with the CONSORT (Consolidated Standards of Reporting Trials; http://www.consort statement.org/about-consort) and STARD (Enhancing the Quality and Transparency of Health Research; http://www.equator network.org) reporting guidelines for clinical trials. In this methodological clinical study, the precision of three different scan-bodies used for the full digital workflow production of the same fixed prostheses with two implants was comparatively evaluated in the clinical and virtual environment. Three scan-bodies used; Group-I: one original scanning post produced by the manufacturer of the dental implant (CARES Mono Scanbody; Straumann Holding AG), Group II: non-original produced by 2 different manufacturers compatible with the dental implant (Scanbody 2.generation; MEDENTIKA GmbH, Hügelsheim,Germany) and generic (3Shape Scanbody, 3Shape A/S) scan posts. Randomization was applied using a free-access internet-based application (Research Randomizer; http://www.randomizer.org) to determine the order of the scan-bodies, and the direct digitalization process of three different scan-bodies was completed in a single session for the same fixed prostheses production in accordance with the specified order. Then, the restorations designed in the CAD step were transferred to the CAM unit and produced without a model in the form of a full contour using the subtractive technique. Primary data were obtained by the qualitative evaluation of the restorations in the clinic, and secondary data were obtained by analyzing the scan post surface data obtained with direct digitalization using the "reverse engineering" process. With these data, the precision of Group I and Group II scan-bodies was evaluated comparatively. This study was accepted by the Hacettepe University Clinical Research Ethics Committee (protocol code: KA-19091) and was approved by the Ministry of Health, Turkish Medicines and Medical Devices Agency. (No: E.471606) The patients were informed in detail about the procedures to be applied and their participation was ensured by signing the informed consent form. No additional fee was requested from the patients. The study was partially supported by Hacettepe University Scientific Research Projects Coordination Unit (project no: 18710). The intraoral scanner 3Shape TRIOS3 (3Shape A/S) was supplied by 3Shape Middle East & Turkey.

Sample Size and Power Analysis: In order to optimize the data to be obtained in the study at the desired effect level, the analyzes were performed using the Repeated Measures Anova method. The sample size for the restorations to be included was calculated using the same method, in order to significantly determine the effect width of 0.33 units (partial eta-squared=0.10) at 80% power and 5% type 1 error level, and it was decided to include at least 25 volunteers in the study. Power analysis calculations were made using G*Power 3.1 software.

Statistical Analysis: Statistical data analysis in terms of lower/upper jaw location of different scan posts and fixed prosteheses, which are thought to be important on quantitative and qualitative data, was performed with Chi-square test using IBM SPSS 23 software. The conformity of quantitative variables to normal distribution was examined using the Shapiro-Wilk test of normality. Mean and standard deviation were used as descriptive statistics for quantitative variables with normal distribution, and median, smallest, largest and interquartile range values were used for non-normally distributed variables. Qualitative variables were defined with numbers and percentages. In terms of quantitative measurements, comparisons between groups were used in cases where parametric test conditions were met (conformity to normal distribution). Statistical significance level was determined as 0.05 in the study.