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(Research Article)

Methodology for metrological evaluation of accuracy and precision in digital and analog dental restoration manufacturing technologies based on international standards

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Abstract

This article presents an extended methodology for the metrological evaluation of the accuracy and precision of digital and analog technologies for manufacturing dental restorations. The proposed approach is based on international standards ISO 12836:2015 and ISO TR 20896-2:2023 and is supplemented by the analysis of the influence of critically significant factors, including the operator factor, scanning parameters (length and trajectory), and environmental conditions. The statistical procedures for data processing, covering normality testing (Shapiro–Wilk test) and the application of group comparison criteria (ANOVA, Kruskal–Wallis), are detailed. Modern requirements for the metrological control of digital scanning devices and traditional gypsum models are summarized, procedures for equipment calibration and sample preparation are described, methodologies for quantitative assessment of trueness and precision are elaborated, and approaches to statistical analysis and interpretation of results are provided to ensure high reproducibility and objectivity in dental laboratory research.

Keywords: Dentistry; Dental Restoration; ISO Standards; Manufacturing Technologies; Comparison Analysis

1. Introduction

The accuracy of reproducing the geometric parameters of dental structures is a critically important factor directly influencing the clinical longevity of restorations and minimizing cement microleakage, as confirmed by numerous studies evaluating marginal gaps and internal adaptation of prostheses [10]. With the advancement of digital technologies in dentistry, including CAD/CAM systems and intraoral scanners, there has been an urgent need for standardized metrological protocols for objective comparison of their performance characteristics and evaluation of the quality of acquired data [8, 9].

Existing literature indicates a significant influence of several factors on the accuracy of digital impressions. These include operator experience [3, 11], scanning length and trajectory [5, 12, 14], as well as environmental conditions such as temperature and humidity [6, 13, 15]. Comprehensive analysis of these factors and their consideration in metrological protocols are crucial for ensuring the reliability and reproducibility of measurement results.

The aim of this work is to present a detailed and comprehensive methodology for the metrological evaluation of digital and analog dental restoration manufacturing technologies, which considers international standards and empirically proven influencing factors, thereby ensuring high objectivity and applicability of the obtained data.

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2. Materials and Equipment

For the implementation of the proposed methodology, the following normative documents, equipment, and materials are used:

2.1. Normative Documents

- **ISO 12836:2015:** Dentistry — Digitizing devices for CAD/CAM systems — Test methods for assessing accuracy [1].
- **ISO TR 20896-2:2023:** Dentistry — Digital impression devices for existing dentition and edentulous jaws — Part 2: Guidance on testing intraoral scanners [2].

2.2. Equipment

- **Reference Laboratory Scanner:** A high-precision contact or optical 3D scanner (accuracy ≤ 5 μm), calibrated according to the manufacturer's protocol. Used as a reference device to obtain high-accuracy CAD models.
- **Tested Scanner:** An intraoral scanner or a laboratory scanner with the latest software version.
- **Calibration Artifacts:** Standardized prismatic and spherical reference objects with known and precisely measured linear and angular parameters, made from a stable material (e.g., titanium or ceramic) with minimal tolerances (≤ 1 μm). Used for evaluating linear and volumetric errors.
- **Odontometry Tools:** A digital caliper with an accuracy class of 0.01 mm for verifying key linear parameters of samples and reference objects.

2.3. Materials

- **High-strength Dental Plaster Class IV:** For manufacturing standard test models, ensuring minimal deformation and high dimensional stability.
- **High-strength Photopolymers:** For manufacturing test models using 3D printing (if evaluating the digital model manufacturing protocol).

3. Methodology

- The proposed methodology includes the following steps: preparation and calibration of equipment and samples, conducting measurements, data processing and statistical analysis.

3.1. Preparation and Calibration

3.1.1. Microclimate Control

- All scanning procedures and storage of test models are carried out under controlled microclimate conditions: temperature (20±2, ∘C) and relative humidity (50±10). These conditions ensure the dimensional stability of gypsum and polymer samples, minimizing thermal and hygroscopic deformations. 1.2.

3.1.2. Calibration of the Reference Laboratory Scanner

- Scanning of the reference artifact in accordance with ISO 12836:2015. 1.2.2. Calculation of linear and angular deviations. Acceptable values are established according to manufacturer specifications and the standard (typically up to 15 am). 1.2.3. Evaluation of precision by five repeated scans of the same reference artifact without changing its position. 1.3.

3.1.3. Calibration of the Tested Scanner

- Performed according to the manufacturer's recommendations and ISO TR 20896-2:2023 specifications. 1.4.

3.1.4. Preparation of Test Models

- Standardized test models (e.g., dental arch phantoms, models with prepared teeth) are fabricated from homogeneous mixtures of Class IV gypsum or high-strength photopolymers following the manufacturer's protocol to minimize deformations.

4. Measurement Protocol

4.1. Trueness Evaluation

- Obtaining a point cloud of the test model using the tested scanner. 2.1.2. Comparison of the obtained point cloud with the reference CAD model (obtained from the reference scanner) in specialized metrology software (e.g., Geomagic Control X [4]). 2.1.3. Quantitative evaluation of trueness by calculating the Root Mean Square (RMS) deviation and the average linear error between the compared surfaces.

4.2. Precision Evaluation

- Performing five repeated scans of the same test model using the tested scanner with identical parameters. 2.2.2. Quantitative evaluation of precision by calculating the standard deviation of the RMS values between the obtained point clouds of each of the five scans.

4.3. Analysis of Influencing Factors

4.3.1. Influence of Scanning Length and Trajectory

- Conducting trueness and precision measurements on models of different lengths (single crown, quadrant, full arch) using various standardized scanning trajectories (e.g., S-shaped, linear, circular).

4.4. Influence of Operator Factor

- Comparing measurement results obtained by operators with different levels of experience (e.g., novices, experienced users), evaluating scanning time and data quality (trueness, precision). 2.3.3.

4.5. Influence of Environmental Conditions

- Conducting measurements under controlled changes in temperature and humidity within the ranges allowed by standards, recording scanning time and error values.

5. Data Processing and Statistical Analysis

5.1. Normality Testing

Before applying parametric statistical tests, the Shapiro–Wilk test is performed to check for normality of error distribution. The null hypothesis (H_0) of normal distribution is accepted if the p-value > 0.05. 3.2. Group Comparison: 3.2.1. If normality of distribution is confirmed, one-way analysis of variance (ANOVA) is applied to assess the statistical significance of differences between multiple groups of scans (e.g., comparing different scanners, operators, or conditions). 3.2.2. In cases where the data deviate from a normal distribution, the non-parametric Kruskal–Walli's test is used for comparing independent groups. 3.3. Visualization: Color deviation maps, generated by metrology software, are used for visual representation of maximum error zones and spatial distribution of deviations.

6. Discussion

The presented methodology provides a standardized and comprehensive approach to metrological evaluation in dental laboratory practice. Adherence to international standards ISO 12836 and ISO TR 20896-2 is fundamental for obtaining comparable and reproducible results in studies of digital system characteristics.

The analysis of the influence of the operator factor, scanning parameters, and environmental conditions, included in the methodology, allows for the identification and quantitative assessment of the contribution of these variables to the final accuracy. The obtained data can be used to optimize working protocols, develop staff training programs, and select equipment considering the specifics of clinical and laboratory practice.

The application of rigorous statistical methods, including normality testing and the use of both parametric and non-parametric comparison criteria, ensures the reliability and validity of conclusions drawn from the research. Data visualization through color deviation maps is an effective tool for qualitative assessment and demonstration of results.

7. Conclusion

The proposed methodology represents a scientifically grounded and practically applicable protocol for the metrological evaluation of the accuracy and precision of dental restoration manufacturing technologies. The integration of international standards, detailed calibration and sample preparation procedures, as well as comprehensive statistical analysis, including the assessment of key influencing factors, ensures high objectivity and reproducibility of laboratory tests. The implementation of this methodology contributes to improving the quality of dental restorations and provides a reliable basis for scientific research in the field of digital and analog dentistry.

Compliance with ethical standards

Disclosure of conflict of interest

No conflict of interest to be disclosed.

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