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Outdoing best-fit approaches for the manufacturing accuracy evaluation of complete denture bases

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(Article begins on next page)

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Title

Outdoing best-fit approaches for the manufacturing accuracy evaluation of complete denture bases

Abstract

Purpose: To compare the reference geometry approach to the best-fit (or superimposition) approach in the estimation of geometric accuracy relevant to the digital and the analog workflow to fabricate a complete denture.

Materials and Methods: Starting from a model of an edentulous maxilla, the two measuring methodologies were tested to estimate the geometric accuracy of the intaglio surface of the complete dentures fabricated by CNC milling and injection molding. Eight areas of interest (AOI) were defined at the intaglio surface of the denture base; a sensitivity analysis determined the minimum number of measuring points to calculate a reliable $\overline{\Delta}$ error value. A repeatability analysis was performed to assess the consistency of this experimental reference geometry approach with respect to the clinic acceptable requirements.

Results: For the analog workflow, the comparison of the reference geometry results to the best-fit results showed a -76 (post-dam)÷169 µm (right flange) range of the $\overline{\Delta}$ mean value for the reference geometry approach, to be compared to -15 (left crest)÷146 µm (right tuberosity) range for the best-fit approach. For the digital workflow, the same comparison showed a -21 (left crest)÷51 µm (left flange) range for the reference geometry approach, compared to a -20 (left crest)÷23 µm (left flange) for the best-fit approach.

Conclusion: The best-fit approach results in an underestimation of mean Δ error values and their distribution over the entire prosthesis. The reference geometry approach correctly estimates error values while focusing on the identification of sources of errors in the manufacturing process.

Keywords: Complete dentures, Digital manufacturing, CAD-CAM, accuracy, best fit, RPS

1. Introduction

There is growing interest in creating complete dentures with digital technology because removable dentures will be important for recovering masticatory function in elderly individuals of the forthcoming super-aged society. Since 1994 [1] 3D laser lithography has been used to manufacture complete dentures. Subsequently, a study [2] proposed the duplication of a complete denture using a computerized numerical control (CNC) machine, using modeling wax; the authors reported the limitations of the technique and that further enhancements were necessary. Several in vitro studies followed these initial attempts to use CAD-CAM technology to fabricate complete dentures [3–9]. In 2012, Goodacre et al. [10] reported a digitally manufactured complete denture from clear plastic using a three-axis milling machine. Also in 2012, studies investigated the accuracy of denture bases manufactured with digital technology [11]. Inokoshi et al. [12] reported that both conventional (analog) and digital procedures for manufacturing complete dentures were sufficiently accurate for clinical application. Srinivasan et al. [13] compared manufacturing methodologies and concluded that after incubation the intaglio surface of five specific regions of interest of complete denture bases showed deviations < 0.1 mm, within a clinically acceptable range. Goodacre et al. [14] investigated the tooth movement of pack-and-press, fluid resin, and injection fabricating techniques to document the most accurate method of prosthesis production. Two in vivo studies [15, 16] investigated patients' satisfaction scores and the retention of digital complete dentures; both found significant differences between analogically and digitally fabricated complete dentures.

Aiming to evaluate the geometric accuracy of dentures, the metrological approach based on superimposition (best fit) became the gold standard of measuring methods. However, this methodology, which responds to the actual needs for immediate execution by operators with basic metrological knowledge (i.e. dental technicians and clinicians), has strong limitations and is not similarly widespread in metrological and production practices for the evaluation of manufacturing process performances.

To reduce such limitations, this paper aims to describe an alternative approach - hereinafter referred to as reference geometry approach (based on Reference Point System-RPS alignment) - to evaluate the accuracy in the digital and analog workflow and show its advantages, by comparing it to the current gold standard. Differently from previous studies in dentistry the proposed approach also implements a reproducible definition of the Areas of Interest (AOI), and the definition of the optimized number of sampling points per each AOI, necessary to significantly estimate the geometric deviations.

2. Materials and methods

This pilot study evaluated two different measuring protocols (Reference geometry and superimposition approach) applied to two different manufacturing protocols (Digital and analog), Fig. 1.

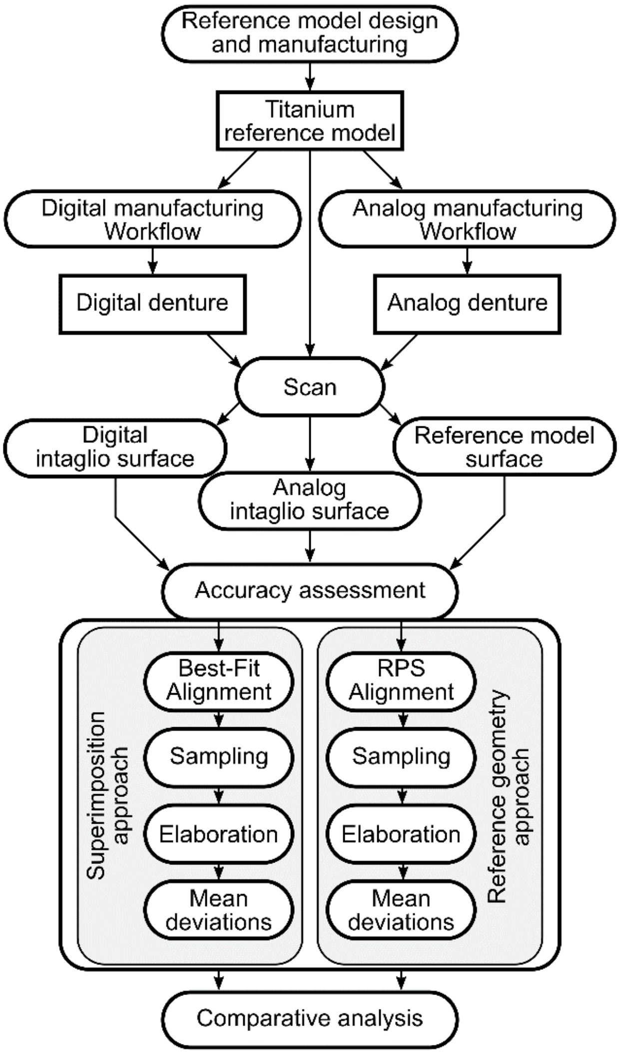

Fig. 1. Workflow of the pilot study.

In brief, a titanium reference model is designed starting from an actual edentulous maxilla and manufactured (section 2.1). The reference model is used as a common starting point for both manufacturing processes (section 2.2) obtaining both digital and analog denture bases. Denture bases and the reference model are 3D scanned obtaining the digital and analog intaglio surface and the calibrated reference model intaglio surface (section 2.3). Both the reference geometry approach and superimposition approach are followed; each of them consists of four phases: alignment (best fit or RPS alignments based on the approach), sampling (based on the sensitivity analysis - section 2.4), elaboration (determination of normal deviation of each sampled point), and determination of mean deviation.

2.1. Reference model design and manufacturing

For the design and manufacturing of the reference model, an actual edentulous maxilla from a stone model library was digitally scanned (E2, 3D-Shape, Erlangen, Germany). The digital model was modified by adding five landmarks (conical surfaces) in the positions of the first molars, canines, and central papilla (Fig. 2). All cones were equal in height and parallel, with the apex at diverse levels according to the mucosal margin of the stone model.

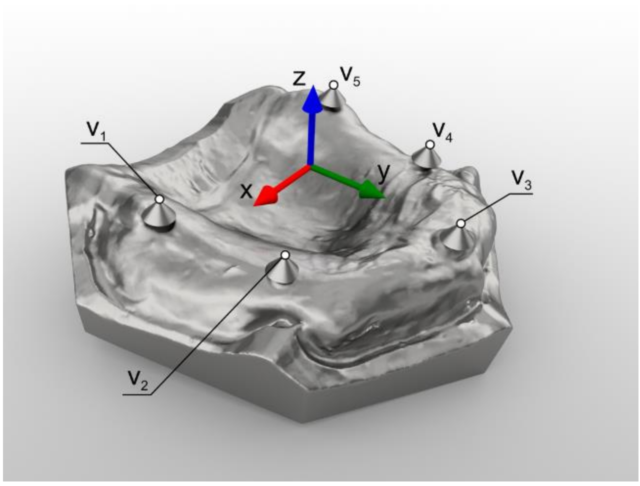

Fig. 2. Geometric landmarks and the spatial reference system.

After the designing phase, the metal reference model was manufactured using a laser melting 3D printing process (EOS M280, EOS, Krailling, Germany) with titanium powder (Ti-6Al-4V grade 23) and was buffed to smooth the surface (Fig. 3).

a) b)

Fig. 3. a. Frontal view of the titanium model with the conical landmarks; b upper view with landmarks at the molars, canines, and central papilla area.

2.2. Denture bases manufacturing processes

The reference model was scanned using a laboratory scanner (E2, 3Shape, Copenhagen, Da) by the authors; the obtained STL file was sent to the manufacturer (Ivoclar). The digital denture base was done according to the Ivotion Denture system protocol (Ivotion, Ivoclar, Schaan, Liechtenstein).

The conventional manufacturing of a second denture base was done according to the injection molding workflow.

2.3. Measurement protocol

According to the workflow (in Fig. 1), the accuracy assessment was performed by using a metrological software (GOM Inspect, Carl Zeiss GOM Metrology GmbH, Braunschweig, Germany) for both approaches.

The reference geometry approach requires to individuate a model 3D reference system (i.e., a tridimensional XYZ cartesian coordinate system, Fig. 2) which was based on the five conical landmarks (V_1 to V_5). A plane fitted to the landmarks geometries (V_1-V_2-V_3-V_4-V_5) was used, for the definition of the origin and orientation of the Z-axis. The landmarks V_1-V_2-V_4-V_5 defined the origin position of the X-Y-axes. The landmark V_3 was used to define the reference system orientation (Y-axis direction). The result was the complete definition of an XYZ cartesian coordinate system (Fig. 2).

The reference model was calibrated using a metrological laboratory scanner (Aurum3D, OpenTechnologies, Bergamo, It) to create the digital reference model surface.

Eight areas of interest (AOIs), for the accuracy evaluation of dentures, were defined at the intaglio surface of the digital reference model surface: right and left edentulous crests, right and left buccal flanges, central palate, postdam, and right and left tuberosity (Fig. 4). According to previous studies [13], these areas were chosen for clinical reasons, because of the typical localization in those sites of sore spots and ulcerations of the mucosa of the complete denture wearers. From a geometrical point of view, the identification of each AOI is based on the projection of a rectangular area on the digital reference model surface. The areas are defined on the reference system planes.

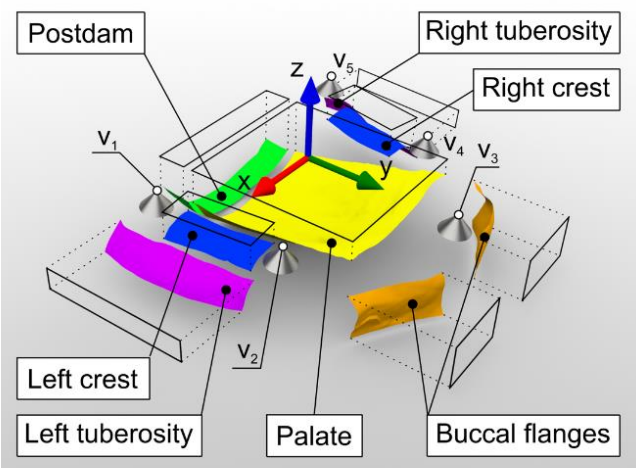

Fig. 4. Areas of interest and relative projections on the sagittal and horizontal planes.

In each area of interest, the measurement point sampling (i.e., the point density or the sampling distance) was determined by sensitivity analysis. In each point, the deviation of the position between the prosthesis surface and the reference model surface was calculated as the distance (linear deviation) along the direction normal to the reference model surface. The mean value of distance ($\overline{\Delta}$) with its standard deviation (SD) were calculated for each AOI.

Similarly, the digital and analog complete dentures were scanned using a metrological laboratory scanner (Aurum3D, OpenTechnologies, Bergamo, It) to create the digital intaglio surface of the denture bases.

To align the digital intaglio surface of the denture base to the digital reference model surface, in the proposed reference geometry approach the landmarks of the denture base are aligned to the calibrated landmarks in the digital reference model surface, using a RPS algorithm.

To compare the two methodologies (reference geometry approach vs superimposition), the best-fit alignment results were also calculated.

2.4. Sensitivity analysis

To set the optimal measurement point sampling, a sensitivity analysis was performed. Point sampling was investigated from 5 mm to 0.6 mm. The optimal point sampling was identified in 1 mm.

With this sampling 91 points were analyzed for the right and left crests, 84 points for the right flange, 78 for the left flange, 840 points for the palatal area, 112 points for the post-dam, 63 points for the right tuberosity, and 88 points for the left tuberosity area.

2.5. Repeatability analysis

To assess the precision of the measurement protocols (reference geometry approach and superimposition approach), ten consecutive measurements of the same intaglio surface of a digital complete denture were executed. A Gage R&R study (crossed) analysis in Minitab was performed; the AOIs were set as different items, and the operator term was not assigned. The reference system stability was evaluated by determining the repeatability of the vertex positions of conical landmarks.

2.6. Measurement values conventions

To better represent the over- or under-contouring of the intaglio surface, all values were discriminated as positive (+ values) deviation for overcontouring and negative (- values) for undercontouring deviation.

3. Results

As concern the preliminary sensitivity analysis, aiming at assessing the optimal point samplings, the mean deviation $\overline{\Delta}$ kept stable (within 5 μm range) as shown in Fig. 5 with the adopted value (1 mm) independently of the AOIs.

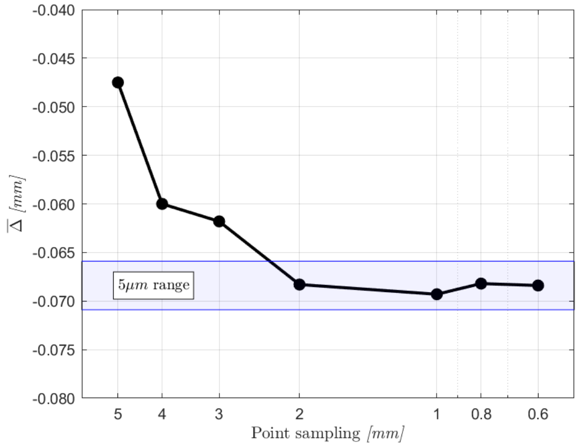

Fig. 5. Example of the sensitivity analysis result (right crestal area).

The repeatability analysis showed that the proposed reference geometry approach has a repeatability (standard deviation) equal to 1.3% of the clinical tolerance (+300 µm, to avoid painful injury to the mucosa) and 9.8% of the range of measures; moreover, the position of the conical landmarks has a standard deviation of 12 µm. The best-fit measuring procedure showed a repeatability of 0.5% of the clinical tolerance and 4.6% of the range of measures; the position of the conical landmarks had a standard deviation of 13 µm.

For each area, the mean deviation $\overline{\Delta}$ and the standard deviation were calculated (Table 1). A positive value deviation $\overline{\Delta}$ indicates a manufacturing allowance, i.e., a local excess of material, or over-contouring, while a negative value indicates a lack of material, or under-contouring.

Results relevant to the geometry reference approach show that in the analog (injection molding) workflow, the values were 53 µm for the left tuberosity area, -45 µm for the left crestal area, 118 µm for the left flange, -67 µm for the palatal area, -76 µm for the post-dam area, 169 µm for the right flange, -27 µm for the right crestal area, and 80 µm for the right tuberosity. In the digital workflow, the mean deviations were 6 µm, -21 µm, 51 µm, 6 µm, 3 µm, 8 µm, 1 µm, and 20 µm, respectively. All values were within the tolerance limit of 300 µm [17], under which the visco-elastic behavior of the mucosa compensates for the localized over-pressure of the complete denture base, without causing any sore spot or ulceration to the mucosal epithelium.

The comparison between the two measurement approaches was calculated as the difference between the results relevant to the superimposition approach minus the results relevant to the proposed reference geometry approach; Table 1 shows the differences as percentage values. For the analog workflow, the minimum $\overline{\Delta}$ was found in the postdam (-76 µm) and the maximum in the right flange (169 µm) with the reference geometry approach; with the superimposition approach, the minimum was found in the left crest (-15 µm) and the maximum in the right tuberosity (146 µm). For the digital workflow, the same comparison showed a -21 µm (left crest) to 51 µm (left flange) range of $\overline{\Delta}$ for the reference geometry approach, compared to a -20 µm (left crest) to 23 µm (left flange) range for the superimposition approach (Table 1).

4. Discussion

Several recent studies have discussed the accuracy (trueness and precision) of digital dentures: all used the best-fit tool [18–24] of commercial software to superimpose digital intaglio surface points of the denture base to the reference model surface.

With the abovementioned aim, a first metrological issue concerns the definition of the target measurement (i.e., AOI) area in a tridimensional curved surface, like that of a maxillary mucosa. Each AOI of the maxillary mucosal surface was determined as the projection of a bi-dimensional geometry (rectangle) from one of three coordinate reference planes onto the surface: the right and left crest, central palate, and post-dam areas were projected from the horizontal plane (x-plane), whereas the right and left flange and tuberosity areas were projected from the sagittal plane (y-plane) (Fig. 4). It is worthy to observe that the protocol guarantees a precise and, therefore, reproducible, definition of AOI dimensions and locations, which represent strong requirements in technical process-related investigations, where highly deformed prosthesis surfaces are evaluated against a reference model, as well as in clinical studies taking into consideration a population of different patient-specific devices.

Table 1. Comparison between the evaluation approaches for the analog (a) and digital (b) workflow. Per each approach, the mean deviation and standard deviation for all AOI are presented. The comparison column shows the differences (superimposition approach values minus reference geometry approach value) in percentage.

a: ANALOGIC workflow

Area	Reference Geometry Approach		Superimposition Approach		Comparison	
	$\overline{\Delta}_{RGA}$ *[mm]*	SD_{RGA} *[mm]*	$\overline{\Delta}_{SA}$ *[mm]*	SD_{SA} *[mm]*	$\Delta(\overline{\Delta})_{\%}$	$\Delta(\mathrm{SD})_{\%}$
Left Tuberosity	0.053	0.034	0.038	0.029	-29.4%	-16.4%
Left Crest	-0.045	0.037	-0.015	0.025	-65.9%	-31.8%
Left Flange	0.118	0.029	0.028	0.025	-76.5%	-11.9%
Palate	-0.067	0.014	-0.002	0.020	-96.6%	41.7%
Postdam	-0.076	0.016	-0.005	0.028	-93.3%	79.9%
Right Flange	0.169	0.024	0.112	0.021	-33.8%	-11.6%
Right Crest	-0.027	0.043	0.046	0.047	67.9%	9.5%
Right Tuberosity	0.080	0.023	0.146	0.024	81.8%	3.2%
Max	0.169	-	0.146	-	-13.5%	-
Min	-0.076	-	-0.015	-	-79.9%	-
Range	0.244	-	0.161	-	-34.1%	-

b: DIGITAL workflow

Area	Reference Geometry Approach		Superimposition Approach		Comparison	
	$\overline{\Delta}_{RGA}$ *[mm]*	SD_{RGA} *[mm]*	$\overline{\Delta}_{SA}$ *[mm]*	SD_{SA} *[mm]*	$\Delta(\overline{\Delta})_{\%}$	$\Delta(\mathrm{SD})_{\%}$
Left Tuberosity	0.006	0.009	0.002	0.011	-60.0%	27.2%
Left Crest	-0.021	0.016	-0.020	0.013	-7.1%	-18.5%
Left Flange	0.051	0.012	0.023	0.011	-53.8%	-5.4%
Palate	0.006	0.016	0.003	0.014	-51.2%	-11.8%
Postdam	0.003	0.022	0.009	0.025	247.4%	11.2%
Right Flange	0.008	0.013	-0.001	0.014	-88.4%	8.3%
Right Crest	0.001	0.015	-0.013	0.016	1348.0%	8.2%
Right Tuberosity	0.020	0.012	0.007	0.009	-63.4%	-22.4%
Max	0.051	-	0.023	-	-53.8%	-
Min	-0.021	-	-0.020	-	-7.1%	-
Range	0.072	-	0.043	-	-39.9%	-

Once the AOIs are defined, a second metrological issue arises, which concerns the definition of the minimum number of points for each AOI, necessary to significantly estimate the $\overline{\Delta}$: this was evaluated in terms of measurement points spacing (sampling), using sensitivity analysis. The distribution of $\overline{\Delta}$ values as a function of the point sampling was generated from the sensitivity analysis (Fig. 5) for each AOI. The distribution diagram is approximated by a linear and horizontal regression line from the optimal measurement spacing distance on. This value determines the minimum number of points necessary to estimate $\overline{\Delta}$ when no further augmentation of the number of measurement points (i.e., reduction of point sampling) causes a significant variation (a threshold equal to 0.005 mm is assumed) in the $\overline{\Delta}$ value. In this pilot study, the sensitivity analysis enabled the determination of an optimal or minimum number of points to analyze for each AOI: 91 points for the right and left crests, 84 points for each flange, 840 points for the palatal area, 112 points for the post dam, and 62 points for each tuberosity.

This pilot study focused on the comparison between a measurement approach based on reference geometry landmarks and the gold standard (superimposition approach). The repeatability analysis demonstrated that the reference geometry approach was effective. The variability was 1.3% of the clinical tolerance and 9.8% of the range of measures. The superimposition approach showed a variability of 0.5% of the clinical tolerance and 4.6% of the range of measures. The variabilities of the two approaches have the same order of magnitude; furthermore, they show a similar repeatability of the reference system position. Therefore, the proposed methodology is reliable and as repeatable as the gold standard.

Comparison of the reference geometry approach to the superimposition approach highlights pros and cons of the methodologies (Table 1).

The main difference concerns the $\overline{\Delta}$ of AOIs and in the overall. For both the manufactured samples (analog and digital), the overall $\overline{\Delta}$ was lower when determined with the superimposition approach than with the reference geometry approach. For the analog denture, the maximum $\overline{\Delta}$ decrease was 13.5% and the minimum $\overline{\Delta}$ was 79.9% with an overall range contraction of 34.1%. The digital workflow showed a range reduction of 39.9%. As expected, the best-fit alignment (superimposition) approach significantly limits the overall mean deviation $\overline{\Delta}$: measures estimated with superimposition are underestimated with respect to the reference geometry approach in the overall surface as well as for the majority of AOIs.

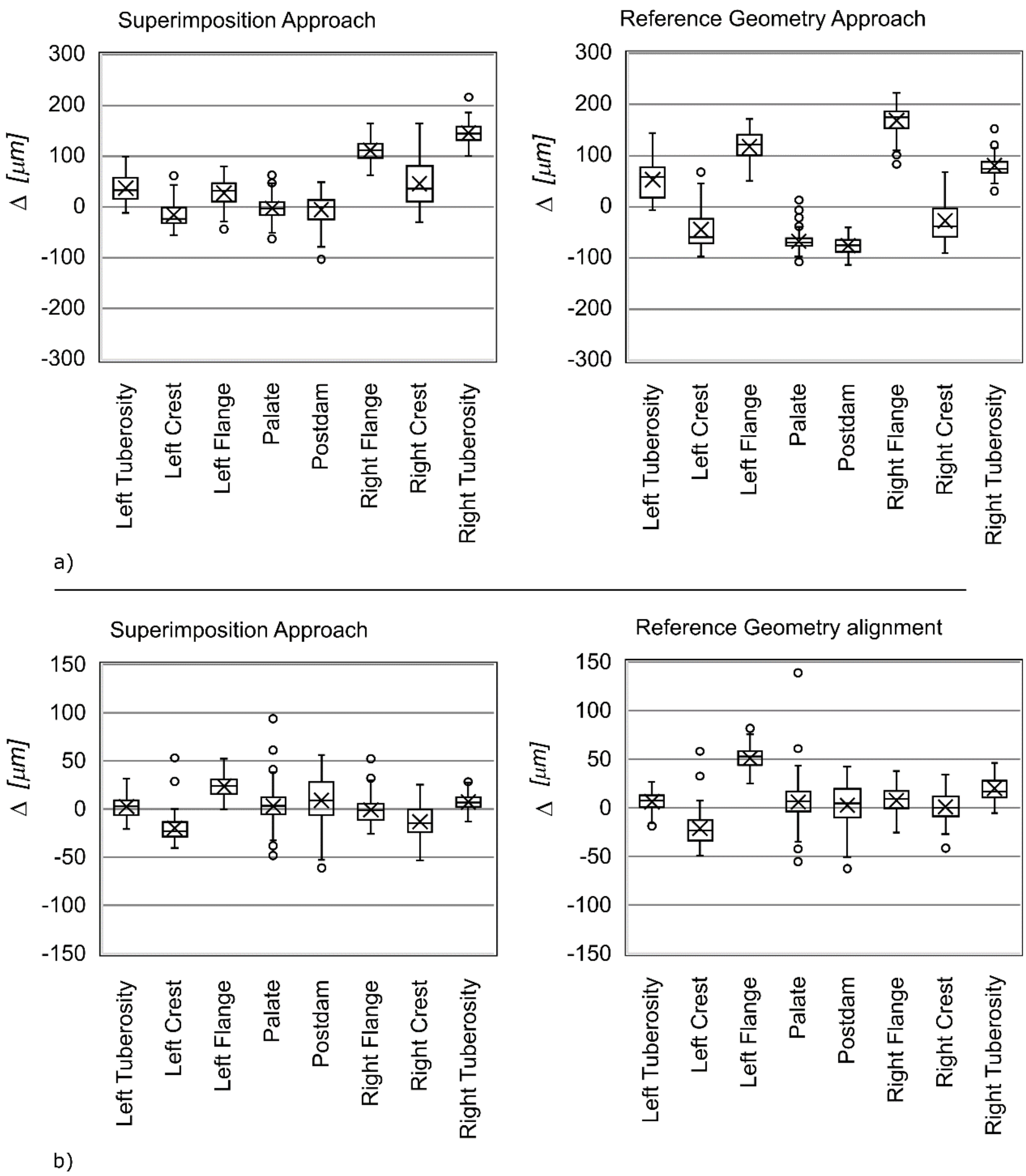

Fig. 6. Box-plot representation of $\overline{\Delta}$ in AOIs for analog (a) and digital (b) prosthesis. Comparison of results relevant to Superimposition and Reference Geometry approaches.

In the case of large deformations, as they result with the analog workflow, since best-fit alignment (superimposition) minimizes the overall deviation $\bar{\Delta}$, the $\bar{\Delta}$ range is consequently reduced while differences in $\bar{\Delta}$ between AOIs become statistically not significant. Conversely, the reference geometry approach succeeds in amplifying error distribution and thus making feasible the identification of highly deformed AOIs, a-/symmetric error distribution on correspondent left-right AOIs, and correct error estimation in AOI with the predominant number of measurement points.

As an example, if we consider the left flange of the analog protocol, the absolute mean value was 118 μm for the reference geometry method, and 28 μm for the best-fit protocol. For both manufacturing protocols, six out of eight areas showed a reduction in $\bar{\Delta}$ value. As a first consequence, the superimposition approach does not point out the AOI where the deviation error is mainly evident and/or symmetrically distributed.

With the reference geometry approach, each AOI can be analyzed independently, and symmetrical behavior can be noted (Fig. 6). It does emphasize the symmetric error distribution, in the analog protocol, while points out the most relevant deformation on the left side, -21 μm (crest), 51 μm (flange), for the digital protocol.

Concerning the influence of the AOI aerial extension, in this study, the AOI relevant to the palate was much larger than the others. With the best-fit alignment, the larger AOI strongly influences the overall results as much as the deviation $\bar{\Delta}$ of any single AOI. This was evident for the analog protocol, with the superimposition which minimize the error of the larger AOI thus determining a palate deviation $\bar{\Delta}$ equal to -2 μm compared to -67 μm using the reference geometry approach. Therefore, if the palate has an actual geometrical error, being the largest area, with superimposition its deviation $\bar{\Delta}$ is actually set to zero when compared to other AOI deviations (Fig. 7).

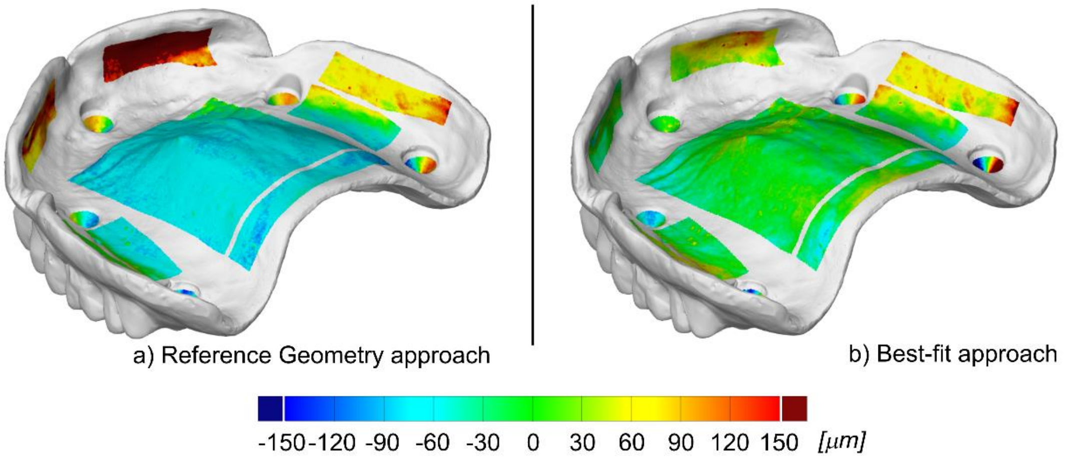

Fig. 7. Color maps of error distribution over the AOIs.

The standard deviation associated with each AOI was less sensitive to the approach used. The relative differences were smaller than that in the mean deviation and no pattern was evident. In both cases, the standard deviation increased in four areas and decreased in four areas.

From a manufacturing point of view, through a process-oriented definition (dimensioning and positioning) of the reference geometries, it was possible to discriminate in which directions the manufacturing protocols are affected by the maximum error. For the analog workflow, the highest absolute value of $\overline{\Delta}$ was in the right tuberosity area (117 µm) for the x- and z-axes, and in the right flange area (33 µm) for the y-axis. For the digital workflow, the highest absolute value of $\overline{\Delta}$ was in the left flange area for the x- and y-axes (34 µm and 65 µm, respectively), and the left crestal area for the z-axis (35 µm).

The mean $\overline{\Delta}$ for the digital and analog workflows was highest at the lateral flanges, but all values were lower than the clinically acceptable range for painful injuries that can be expected with compression of > 0.3 mm [17]. As reported by Cook [25] in a study in monkeys, the compressive mucosal displacement under dynamic loading on a maxilla fitted with a denture base is 0.375 to 0.5 mm. Satoshi [26] demonstrated that after the insertion of a complete denture the denture base sinks by ~0.3 mm in the oral mucosa because of the occlusal force without causing mucosal injuries. Therefore, the gap between the intaglio surface of the complete denture base and the original model (digital or analog/gypsum) is clinically acceptable [27].

5. Conclusion

Hence, the superimposition of two surfaces by the best-fit algorithm may have the following limitations, when applied to the evaluation of trueness and precision:

1. The best-fit approach leads to an underestimation of the mean deviation values relevant to the entire prothesis and any AOIs.
2. The underestimation manifests, similarly, for the range of AOIs mean deviations relevant to the entire prothesis; this is not seen considering the standard deviation in an AOI.
3. The source of error may, therefore, be difficult or impossible to identify.

For these reasons, a methodology that considers reference geometries for alignment and errors evaluation was proposed in this pilot study.

A further experimental study is needed to apply the reference geometry approach to the measurement of significant differences between other groups, without using the superimposing procedure.

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