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A new method for assessing the accuracy of full arch impressions in patients

impression procedure in clinical use.



^a Department of Prosthodontics, Justus-Liebig University, Schlangenzahl 14, D-35392 Giessen, Germany ^b Chair, Department of Prosthodontics, Justus-Liebig University, Schlangenzahl 14, D-35392 Giessen, Germany

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ABSTRACT

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digital superimpositions of the spheres with the reference data set were executed. *Results:* With regard to the distance measurements, CI showed the smallest deviations followed by intraoral scanners TD, cT and OC. A digital superimposition procedure yielded the same order for the outcomes: CI $(15 \pm 4 \,\mu\text{m})$, TD $(23 \pm 9 \,\mu\text{m})$, cT $(37 \pm 14 \,\mu\text{m})$, OC $(214 \pm 38 \,\mu\text{m})$. Angle measurements revealed the smallest deviation for TD $(0.06^{\circ} \pm 0.07^{\circ})$ followed by CI $(0.07^{\circ} \pm 0.07^{\circ})$, cT $(0.13^{\circ} \pm 0.15^{\circ})$ and OC $(0.28^{\circ} \pm 0.21^{\circ})$.

Objective: To evaluate a new method of measuring the real deviation (trueness) of full arch impressions

intraorally and to investigate the trueness of digital full arch impressions in comparison to a conventional

Methods: Four metal spheres were fixed with composite using a metal application aid to the lower teeth of 50 test subjects as reference structures. One conventional impression (Impregum Penta Soft) with

subsequent type-IV gypsum model casting (CI) and three different digital impressions were performed in

the lower jaw of each test person with the following intraoral scanners: Sirona CEREC Omnicam (OC), 3 M

True Definition (TD). Heraeus Cara TRIOS (cT). The digital and conventional (gypsum) models were

analyzed relative to the spheres. Linear distance and angle measurements between the spheres, as well as

Conclusion: The new measuring method is suitable for measuring the dimensional accuracy of full arch impressions intraorally. CI is still significantly more accurate than full arch scans with intraoral scanners in clinical use.

Clinical significance: Conventional full arch impressions with polyether impression materials are still more accurate than full arch digital impressions. Digital impression systems using powder application and active wavefront sampling technology achieve the most accurate results in comparison to other intraoral scanning systems (DRKS-ID: DRKS00009360, German Clinical Trials Register).

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1. Introduction

CAD/CAM (computer-aided design/computer-aided manufacturing) technology is very well-established in dentistry, particularly in the production of high resistance all-ceramic restorations. The conventional production of dentures uses elastomeric impression materials and the CAD/CAM production of dental restorations are incorporated by the digitization of plaster models using laboratory scanners (indirect digitization). Although indirect digitization is still the standard procedure in

* *Corresponding author.

E-mail addresses: fabian.j.kuhr@dentist.med.uni-giessen.de (F. Kuhr), alexander.schmidt@dentist.med.uni-giessen.de (A. Schmidt), Peter.Rehmann@dentist.med.uni-giessen.de (P. Rehmann), bernd.woestmann@dentist.med.uni-giessen.de (B. Wöstmann).

http://dx.doi.org/10.1016/j.jdent.2016.10.002 0300-5712/© 2016 Elsevier Ltd. All rights reserved. digital practice [1], it has all of the same deficiencies that conventional impression taking and model casting has. The possibility of scanning inaccuracies by the laboratory scanner is also of concern [2,3]. To avoid the errors of the conventional CAD/CAM-production workflow, performing the digitalization directly in the patient's mouth using intraoral scanners would be more practical.

The accuracy of intraoral scanners has recently been investigated in several studies. In terms of single tooth digital impressions, studies demonstrated equivalent or even better accuracy with intraoral scanners than for conventional impressions [3–6]. To our knowledge, the accuracy (trueness) of full arch scans, necessary for long span restorations, has not been investigated directly in patients due to lack of feasible measuring methods. Furthermore, the few laboratory studies available demonstrate contradictory results [7–13]. Presumably, intraoral







conditions such as saliva, humidity, limited oral space, and patient movement are additionally suspected to influence scanning accuracy [14]. The goal of the present study is to assess the accuracy of a new intraoral measuring method for full arch impressions.

In-vitro studies include different analyzing procedures that are used to investigate the accuracy of full arch digital models. Measuring linear distance between fixed reference structures in a model [13] is a common practice. However, the most commonly employed procedure is three-dimensional analyses generated by superimposing the digital model with a reference model using best-fit algorithms and calculating the mean differences of the surface areas [8–11,15]. For this purpose, a reference model is scanned by high-precision optical or tactile laboratory scanners. In general two factors have been investigated: the "trueness" of the scans describes the scan's deviation from the original object. The "precision" is defined as the differences between repeated measurements [16].

Because the jaw of a patient cannot be assessed with tactile or other high-precision optical laboratory scanners, it is difficult to obtain an accurate reference data set (reference model). Few invivo studies concerning full arch intraoral scans use gypsum casts obtained from conventional impressions as a reference or they only measure the precision of the scans [14,16,17]. Therefore, no conclusion about the real deviation (trueness) of the scans can be drawn. The goal of the presented study was to develop a new measuring method by creating an intraoral reference using reference spheres attached to the teeth of test subjects. Next, this method was implemented to determine the trueness of three digital impression systems (Sirona CEREC Omnicam, 3M True Definition, Heraeus Cara TRIOS) and one conventional impression (Impregum Penta Soft) intraorally. The following null hypothesis was tested: There is no statistically significant difference (p < 0.008) between the four tested impressions systems regarding the determined parameters for dimensional accuracy.

2. Methods

Fifty volunteer subjects (25 m/25 f) with a complete lower dental arch (fully dentate or fixed restorations) were included in the study that was executed in the Department of Prosthodontics of the Justus-Liebig-University, Giessen, Germany. The subjects included in the study had a dental arch shape that allowed for the proper fixation of the reference spheres (s. below). The study was approved by the Ethics Committee of the Justus-Liebig-University Giessen (163/15) and registered in the German Clinical Trial Register (DRKS ID: DRKS00009360).

2.1. Placement of reference spheres

To generate a reference data set, geometrical structures on the teeth with known dimensions and spatial distances were required. Four steel spheres (diameter = 5 mm) were attached to the teeth using a flowable composite (Plurafill flow, Pluradent, Offenbach, Germany) without etching the teeth. Previously the spheres were sandblasted to minimize reflective issues during powder-free scanning and to enhance the retention of the spheres to the teeth. A metallic transfer aid (TA) was manufactured to fix the spheres in each subject consistently in the same predefined spatial relation and distance from each other (Fig. 1). The shape of the TA was based on an average sized lower dental arch [18], the four spheres formed the corners of a symmetrical trapezoid (Fig. 2A). The TA was cut out of a stainless steel blank using a wire eroding machine and thereafter fine-tuned with a 5 axis milling machine (Reinhard Bretthauer, Dillenburg, Germany). The spheres were fixed in four







Fig. 1. (A) Transfer aid with spheres inserted. Application of composite on the spheres. (B) Placing the spheres on the teeth, light curing the composite, magnets are attached with composite to the upper side of the transfer aid. (C) Spheres fixed to the teeth.

round recesses on the underside of the TA by magnets without any movement range.

Prior to the attachment of the spheres, the lower teeth of the subjects were cleaned and completely dried from saliva. Composite was applied on the protruding parts of the spheres (Fig. 1A) and the TA with the spheres inserted was placed on the subject's dental arch (Fig. 1B). After light-curing the composite, the TA was carefully removed and the spheres remained on the teeth (Fig. 1C). To facilitate the procedure, Optragate (Ivoclar Vivadent, Schaan,



Fig. 2. Three different analytical procedures. (A) Measurement of linear distances in between the centres of the spheres ($D1_2$, $D1_3$, $D1_4$, $D2_3$, $D2_4$, $D3_4$) and accuracy of the bonding procedure: Mean \pm SD (95% Confidence Interval). (B) Angle measurement in between the normal vectors of two constructed planes. (C) Superimposition with the reference spheres using a best-fit algorithm.

Liechtenstein) was used to hold the lips back from the anterior teeth.

The accuracy of the bonding procedure was determined in a test setup on a steel model. The deviations of repeated sphere attachments were determined using a high-precision coordinate measuring machine (CMM) (Thome Präzision GmbH, Messel, Germany, MPEe 2.2 μ m + (L/350), where L is the measured length). Ten tests were performed. Regarding the precision of the data (Fig. 2A), with a width of the 95% confidence intervals ranging from $\pm 4.5 \mu$ m (D3_4) to 8.5 μ m (D1_3), it can be assumed that this

procedure is capable of identifying errors of >10 μ m with a 95% certainty (Fig. 2A).

2.2. Scanning and conventional impression-taking

After luting the spheres, three scans of the full lower dental arch were taken with the Optragate still in place. The Scanners CEREC AC Omnicam (OC) (Sirona, Wals, Austria; software version 4.2.4.72301), cara TRIOS (cT) (Heraeus, Hanau, Germany; software version 2013-1) and True Definition (TD) (3M, St. Paul, USA;



Fig. 3. Study set-up.

software version 5.0.2) were used according to the manufacturers recommendations for full arch scans. The scanning sequence started with OC or cT (change every second patient) and was followed by TD scanner. TD was always used at the end of scanning procedure because of the powder application required. Titanium dioxide powder (LAVA Powder for Chairside Oral Scanner, 3M Espe, Lexington, USA) was applied in a thin layer on the teeth and spheres using the recommended powder sprayer (LAVA Sprayer, 3M Espe, Lexington, USA). All scan data were exported to a standard STL-format for further processing.

After scanning and cleaning teeth and spheres from the powder, Optragate was removed. Next, a conventional impression (CI) with a medium body polyether impression material (Impregum Penta Soft, 3M Espe, Seefeld, Germany) was taken in a full-arch metal stock impression tray (Ehricke stainless steel, Orbis Dental, Germany).

During tray removal, the spheres and the composite usually remained in the impression material. Prior to pouring the impression the spheres were removed. The impression was disinfected (MD 520, Dürr Dental AG, Bietigheim-Bissingen, Germany), stored at least 2 h to ensure elastic recovery, and poured with type IV dental stone (Fujirock EP, GC Europe, Leuven, Belgium). The plaster models were stored for 5–7 days at ambient room temperature of 22 °C \pm 1 °C and humidity of 40% \pm 10%.

2.3. Measurement procedure

The reference measurement was performed on the inserted spheres in the TA using the CMM with the corresponding controlling Software (Metrolog XG, Version 13.006). A digital model of the reference spheres was stored as a CAD-file (IGES-file format). The spheres of the plaster models were also measured and digitized with the CMM.

All digital models were analyzed using an Inspection-Software (GOM Inspect-Software V. 7.5, Braunschweig, Germany) for threedimensional-point clouds. With each digital model three different measurements were performed:

- linear distance measurement in between the centres of the spheres (1–4) (Fig. 2A)
- angle in between the normal vectors of two constructed planes defined by spheres 1, 2, 4 and 1, 3, 4 (Fig. 2B)
- superimposition with the reference spheres using a best-fit algorithm and visualization in a colored image (Fig. 2C)

The absolute values of the differences between the measured distances and angles to the reference values were calculated.

Deviations of the aligned surfaces were calculated for both negative and positive values of mean and maximal discrepancies. The entire workflow of the study is depicted in Fig. 3.

2.4. Statistical procedures

For statistical analysis, the absolute values of positive and negative mean deviations were used. The different impression systems were analyzed by means of pairwise comparisons. Therefore, basically all data were statistically evaluated using a paired sample *t*-test to reveal statistically significant differences between the various systems. If the requirements for the *t*-test were not fulfilled, a sign test was used. A Bonferroni correction was applied to take into account that six pairwise combinations were possible under test. Thus the level of significance was set from 5% for one test group to 0.8% (p < 0.008) for a single comparison. The statistical analysis was carried out with SPSS 22.0 for Windows (SPSS Inc., Chicago, USA).

3. Results

A total of 200 models (150 digital models of the three intraoral scanners and 50 gypsum casts) from 50 subjects were analyzed. Tables 1 and 2 summarize the calculated differences between the measured parameters of the tested impression systems along with reference values (trueness).

3.1. Linear distances

With regard to the measured distances, the largest deviations for all impression systems were observed for D1_4, which represents the intermolar distance across the whole jaw. CI showed lower deviations for all distances in comparison to the scanning systems with minimum deviations of $17 \pm 12 \,\mu\text{m}$ (D2_3) and maximum deviations of $43 \pm 30 \,\mu\text{m}$ (D1_4) (significant differences to OC for all of the distances, to cT for five of the distances and to TD for three of the distances). The significant (p < 0.008) highest deviations were found for OC with a value range from minimal $382 \pm 27 \,\mu\text{m}$ (D3_4) to a maximum of $828 \pm 265 \,\mu\text{m}$ (D1_4) (Table 1).

3.2. Angle measurement

The lowest angle deviation was determined for TD $(0.06 \pm 0.07^{\circ})$ without a significant difference to CI (p=0.565). No significant differences in between cT $(0.13 \pm 0.15^{\circ})$ and CI (0.07 ± 0.07) (p=0.322) and in between cT and TD (p=0.041)

Table 1

Deviations (Mean \pm SD in μ m) of the linear distances measured between the spheres 1, 2, 3, 4. Lower table section: results of paired pairwise statistical analysis (n.s. = not significant).

Impression System	D1_2(µm)	D1_3(µm)	D1_4(µm)	D2_3(µm)	D2_4(µm)	D3_4(µm)				
CI	19 ± 13	22 ± 17	43 ± 30	17 ± 12	26 ± 18	18 ± 11				
TD	30 ± 16	47 ± 38	86 ± 73	30 ± 20	45 ± 34	23 ± 14				
cT	49 ± 26	68 ± 42	97 ± 77	31 ± 21	58 ± 49	48 ± 20				
OC	386 ± 22	798 ± 132	828 ± 265	528 ± 75	731 ± 160	382 ± 27				
Paired pairwise statistical analysis (*=t-test, **=sign test)										
CI vs. TD	p < 0.001*	p=0.001**	$p = 0.034^{**}$	$p < 0.001^*$	p=0.034** (n.s.)	$p = 0.012^*$				
CI vs. cT	$p < 0.001^*$	$p < 0.001^*$	p=0.003**	$p{<}0.001^*$	$p = 0.016^{**}$	p < 0.001*				
CI vs. OC	$p < 0.001^*$	$p < 0.001^*$	$p < 0.001^*$	p < 0.001**	p < 0.001*	p<0.001*				
TD vs. cT	p < 0.001*	p=0.021*	p=0.474*	p=0.772*	p=0.066*	p < 0.001*				
		(n.s.)	(n.s.)	(n.s.)	(n.s.)					
TD vs. OC	$p < 0.001^*$	$p < 0.001^*$	$p < 0.001^*$	p < 0.001*	p < 0.001*	$p < 0.001^*$				
cT vs. OC	$p < 0.001^*$	$p < 0.001^*$	$p < 0.001^*$	$p < 0.001^{**}$	$p < 0.001^*$	$p < 0.001^*$				

Table 2

Results (Mean \pm SD in μ m) of the superimposition analysis for maximal positive and negative deviations as well as for the mean positive and negative deviations and their absolute values. In addition, the results of angle measurements between the constructed planes. Lower table section: results of paired pairwise statistical analysis (n.s. = not significant).

Impression System	Max. pos. dev. (µm)	Max. neg. dev. (µm)	🛛 pos. dev. (µm)	🕖 neg. dev. (µm)	⊘ abs. dev. (µm)	Angle (°)
CI	47 ± 24	-59 ± 20	14 ± 7	-17 ± 4	15 ± 4	$\textbf{0.07} \pm \textbf{0.07}$
TD	90 ± 34	-112 ± 45	20 ± 9	-26 ± 11	23 ± 9	$\textbf{0.06} \pm \textbf{0.07}$
сТ	129 ± 39	-124 ± 45	34 ± 13	-41 ± 18	37 ± 14	$\textbf{0.13} \pm \textbf{0.15}$
OC	628 ± 110	-506 ± 107	230 ± 40	-199 ± 42	214 ± 38	$\textbf{0.28} \pm \textbf{0.21}$
Paired pairwise statistical	analysis (* = <i>t</i> -test, ** = sigr	n test)			n < 0.001**	n=0.565*
	p < 0.001				p < 0.001	(n.s.)
CI vs. cT	$p < 0.001^*$				$p < 0.001^*$	$p = 0.322^{**}$
CI vs. OC	p < 0.001*				p < 0.001*	p < 0.001*
TD vs. cT	p=0.025*				p < 0.001*	p=0.041**
	(n.s.)					(n.s.)
TD vs. OC	$p < 0.001^*$				$p < 0.001^*$	$p < 0.001^*$
cT vs. OC	$p < 0.001^*$				$p < 0.001^*$	$p{<}0.001^*$

were observed either. Highest deviations were found for OC (0.28 \pm 0.21 $^{\circ})$ (Table 2).

3.3. Superimpositions

Mean positive and negative deviations of the superimposition procedure of the spheres showed the lowest mean deviation for CI $(15 \pm 4 \,\mu\text{m})$ followed by the scanning systems TD $(23 \pm 9 \,\mu\text{m})$, cT $(37 \pm 14 \,\mu\text{m})$ and OC $(214 \pm 38 \,\mu\text{m})$. The same order can be observed for the average maximal positive and negative deviations. All impression systems showed significant differences to each other (p < 0.008) except TD to cT (p = 0.025).

4. Discussion

4.1. Method

The present study is the first to use a method for assessing the trueness of full arch impressions using a direct intraoral reference. The basic idea of analyzing dimensional changes in full-arch impressions by means of measuring-bodies is applied in several invitro studies [13,19,20]. The application of four metal spheres, fixed on the posterior teeth of a jaw model to determine the dimensional changes in full arch impressions has already been proven in a laboratory study by Vogel et al. [21]. These authors measured linear distances between the spheres to determine the accuracy of scanned alginate impressions. However, this approach only relies on distances in between the spheres and so does not necessarily identify a vertical shift of the spheres. Therefore, in the new approach presented in this study, additional angle measurements and three-dimensional superimpositions with a reference data set were performed. By means of angle measurements, the detection of a positional change of the spheres in vertical direction is certain. The three-dimensional superimpositions fulfill the demands of some authors to analyze dimensional changes of impressions and models with three-dimensional investigation procedures [22,23]. Meanwhile, these superimposition procedures using best-fit algorithms are widely used to determine the accuracy of full-arch impressions. In-vitro investigations superimpose a reference scan of a master model with digital impressions or digitized conventional impressions [8-11,15]. A clear advantage of these superimpositions compared to the method presented is that deviations at any point of the dental arch can be detected. By superimposing the spheres, distortions could only be registered on the spheres

and thus deviations of areas between the spheres were not considered. Alternatively, the use of spheres has the advantage that the reference data set and the gypsum casts could be measured with a CMM, which is a very precise scanning method in comparison to optical laboratory scanners [24]. Güth et al. avoided scan superimposition because of errors caused by superimposition computing processes, especially those in larger data sets such as full-arch scans and for high deviations between the superimposed areas [12]. Apart from computing errors, a best-fit alignment could mask distortions by moving the distorted models in the most optimal position to the reference model. Distance measurements provide information about the absolute deviation and should therefore not be renounced.

A crucial factor to implement the presented measuring method was the accuracy of the attachment procedure of the spheres. The spheres had to be placed in the same spatial orientations for each test person in each attachment process. Factors influencing the correct positioning of the spheres include the exactness of the transfer aid and the appropriate attachment material (and the skill of the operator). Overall, even if the 95% confidence interval for repeated luting procedures in the lab model indicating a measuring accuracy of less than $10 \,\mu m$ across the whole arch is not fully achieved in patients, the procedure developed is still valid. The procedure allows for a measuring accuracy in patients capable of detecting errors in a clinically relevant range. This is especially true for restorations on natural teeth with a regular mobility up to 100 µm [25], and can even be considered relevant for implantborn restorations with an implant mobility of approximately 10 µm [25].

4.2. Data analysis

The distance measurements revealed positive and negative values for CI, TD and cT depending on whether the models were horizontally enlarged or reduced in width. OC only showed positive values in distance measurements, which means that all models of OC were horizontally stretched. By default, the output values of best-fit superimpositions are in the form of positive or negative values to describe the proportion of areas lying above or below the reference data. According to Güth et al., absolute values of the measured deviations were used to determine the trueness of the scans and also for statistical analysis because the calculation of the arithmetic mean with positive and negative values "would have led to results close to zero" [3].

4.3. Results

With a few exceptions there were significant differences between most of the impression systems in the present study with regard to the measured parameters. Therefore, the null hypothesis had to be rejected. Conventional impression taking and model fabrication showed overall better results than the digital impression methods. Very few studies compared the trueness of conventional with digital full arch impressions [9–12]. Some studies showed comparable or even better results for digital full arch impressions than for conventional impressions [9,12]. Other studies showed worse outcomes for the digital impressions [10,11,16], which nonetheless were partially described as sufficiently accurate [11].

Differences between these investigations may be caused by various approaches of measuring procedures. There is no study using an identical measuring method such as the present study, which makes the comparison of the results difficult. The intraoral use of the scanners was an important deviation from all other studies regarding the trueness of full-arch scans. The scanning of the measuring spheres on top of the teeth, considering the limited space available, was particularly challenging.

TD, which is based on Active Wavefront Sampling technology (AWS), showed the best results for all tested intraoral scanners. Other studies investigating the predecessor of the TD Scanner (Lava C.O.S.) also presented the best results for the AWS-scanning system regarding the trueness of the scans [8,13]. In addition to the optical data acquisition technique, the powder application was another difference of TD compared to the other tested intraoral scanners. The powder might be a major advantage because it provides landmarks which could lead to a better matching procedure of the single point clouds during the scanning process. In addition, Ender et al. reported that the powder provides a more regular reflection of the projected light of the scanners because enamel and gingiva have different light reflecting properties [26].

With regard to the angle measurements, TD and cT did not differ significantly from the conventional method. This demonstrates that these scanners produce little vertical distortion but do produce horizontal deviations. Patzelt et al. support this assumption by observing deviations of most of their investigated scanners in horizontal direction, especially in the region of the molars and posterior parts [8]. To demonstrate the effect of the angle deviations measured, a resulting metric vertical error can be calculated (error = tan $\alpha \times 46$ mm): Assuming that the impression error primarily occurred across the whole arch (between sphere 1 and 4) a vertical deviation of 50 µm would result for the lowest angle deviation (0.06°) observed and 225 µm for the highest angle deviation (0.28°). These vertical deviations might be of serious consequence in a clinical application.

OC revealed the largest deviations for all measured parameters among the tested systems. Contradictory results can be found in the literature regarding Cerec-Systems for application in full-arch scans. Regarding three-dimensional superimpositions of OC, Jeong et al. reported a trueness of $197 \pm 4 \,\mu m$ [7], which is approximately comparable to our own results ($230 \pm 40 \,\mu$ m). Ender et al. reported a completely different trueness of $37.3 \pm 14.3 \,\mu m$ [11]. Such differences could already be observed between studies evaluating the trueness value from Cerec Bluecam (Patzelt et al.: $332.9 \pm 64.8 \,\mu\text{m}$ to Ender et al.: $29.4 \pm 8.2 \,\mu\text{m}$) [8,11]. These contradictory results may be due to different statistical analysis, as Ender et al. mostly use 90-10 percentiles to analyze their data. Other explanations for the variations could be different handling of the scanners, different superimposition procedures, or different software versions of the scanners. Additionally, it has to be noted that we used the Crown scanning version of the Cerec software that is primarily intended for small restorations in one quadrant. Probably better results may be achieved using the Cerec orthodontic package implemented in the latest software release.

By scanning single teeth, digital impressions show very accurate and partially better results than conventional impressions [4–6]. Because of the relatively small scanning hand pieces of the intraoral scanners, the entire dental arch cannot be captured in one image. The capture unit of the hand piece has to be moved across each individual tooth of the dental arch, whilst the software of the scanner matches the overlapping single images (point clouds) together. The accumulative error in this matching process is considered to be responsible for the distortions in full arch scans [19,27,28]. It should be noted, that all scans were performed in the lower dental arch. Scanning of an upper arch may lead to better results, especially if the scanning software allows for the scanning of palate and additionally uses the scanned palate for matching. However, the anterior region is especially a potential source of errors because the anterior teeth provide less structure and make an accurate matching process more difficult [10,11,16]. These theories were confirmed by observations revealing that the greatest deviations were found for the distance across the whole arch (distance 1_4) and most scanning errors during the scanning process occurred in the anterior region. These software-induced errors may be amenable without changing optical data acquisition in principle. By improving the matching-algorithms, some scanners could reach the same accuracy as conventional impressions in the near future.

5. Conclusion

It can be concluded that the developed method is suitable for measuring trueness of full arch impressions for both conventional and digital impressions. Deviations $\geq 10 \,\mu\text{m}$ across the whole dental arch can be determined with the presented method. The results of the present study show that for full arch intraoral impressions under clinical conditions, the conventional impression procedure with subsequent model casting is still more accurate than digital impressions with intraoral scanners.

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