



## Original article

Computerized optical impression making of edentulous jaws – An *in vivo* feasibility study

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## ABSTRACT

**Purpose:** Within the specialty of prosthodontics, oral impressions are ubiquitous tools utilized to transfer intraoral characteristics such as teeth, implants, and soft tissue into a physical state (stone cast) that is processable in a laboratory setting for the fabrication of dental restorations. In recent years, optical impression systems have become ubiquitous in clinical practice replacing the conventional method of impression making. The purpose of the present study was to evaluate the feasibility and accuracy of computerized optical impression making of edentulous jaws in an *in vivo* setting.

**Methods:** 29 edentulous patients (27 maxillae and five mandibles) underwent conventional impressions as well as computerized optical impressions. The conventional impressions and the resulting stone casts were digitized and superimposed over the computerized/digitized optical impressions in order to obtain information on differences between the two datasets. Statistical analyses were performed to identify relevant deviations.

**Results:** The overall mean difference between the stone cast, digital scans and the computerized optical scans were  $336.7 \pm 105.0 \mu\text{m}$  ( $n = 32$ ),  $363.7 \pm 143.1 \mu\text{m}$  ( $n = 24$ ), and  $272.1 \pm 168.5 \mu\text{m}$  ( $n = 29$ ), respectively. The visual evaluations revealed highest deviations ( $\geq 500 \mu\text{m}$ ) in the areas of the soft palate, the sublingual areas, and the vestibule (peripheral seal zone).

**Conclusions:** Within the limitations of the present study, the investigated scanners were not able currently to fully replace a conventional impression for the fabrication of a complete denture.

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## 1. Introduction

For almost all manufacturing processes of prosthodontic restorations, an impression, in other words a negative likeness [1], of a tooth, an implant, or the soft tissue is required. Based on this conventional impression, a physical cast, a positive

replica, can be produced and utilized for the fabrication of dental restorations. For over two centuries, this has been accomplished with various types of plastic impression materials (Alginate, Zinc-Oxide-Eugenol, Agar-Agar, Silicones, and Polyether). However, these so called “conventional” impression materials have various inherent problems and disadvantages, which may influence the efficiency of the dental team [2], as well as the quality of the final restoration. Various issues with conventional impressions include: improper tray selection, need for disinfection of the impression,

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separation of the impression material from the impression tray, distortion of the material before pouring, and distortion during storage of the impressions [3,4].

Inspired by the available computer technology in the 1980s, Francois Duret conceptualized a digital approach for computer-aided design/computer-aided manufacturing (CAD/CAM) of dental restorations based on optical scanning of teeth [5]. Mörmann and Brandestini implemented Duret's concept into a commercially available dental device, well known today and still available under the brand CEREC [6–9].

Since the introduction of computerized optical impression making (COIM), several companies have developed similar devices and the indication spectrum of these devices has expanded from small partial single tooth restorations to multi-unit, full-arch restorations. Nevertheless, COIM is still limited to the digitization of prepared teeth, implant abutments, and partially edentulous areas, although completely edentulous jaws are still another common scenario. Edentulous jaws compromise a saliva covered, tissue-based situation with several zones of mobile tissue such as the vestibule and the sublingual areas, combined with a smooth surface texture. In comparison to the digitization of teeth, this totally edentulous situation might be difficult to capture with the currently available intraoral scanners. However, there is only one *in vitro* study available on the feasibility and accuracy of digitizing edentulous jaws. Patzelt et al. [10] investigated four intraoral scanners regarding their ability to capture edentulous study models. These authors identified one scanner (Lava C.O.S., 3M ESPE, St. Paul, USA) to be potentially used for an *in vivo* investigation.

Interestingly, CAD/CAM methods to produce complete dentures based on surface data are already available and utilized in dentistry [11–39]. Nevertheless, the process is still based on making a conventional impression with a custom tray and border molding. Based on this impression, a stone cast is produced and optically scanned for the actual CAD/CAM manufacturing process. This optical impression or cast scan can possibly be easily replaced with a sufficiently obtained intraoral computerized optical impression (COI).

The aim of the present study was to investigate the feasibility and accuracy of COIM of edentulous jaws in an *in vivo* experiment. Additionally, the obtained data was compared to the conventional approach of impression making and the resulting stone casts (gold standard). The null hypothesis ( $H_0$ ) was that there is no difference between conventional impressions, the resulting stone casts, and computerized optical impression making, regarding the retrieved optical surface data.

## 2. Materials and methods

The present prospective clinical feasibility study was conducted at the University of Maryland, School of Dentistry (UMSOD) from January 2014 to August 2014 and approved by the institutional review board (HO-00054462, approved 6/12/2013). The study has been registered in the German Clinical Trials Register (DRKS00008877).

A sample size calculation was performed to determine an adequate number of patients to be included in the study. For this purpose, results from a previous *in vitro* study were used as reference [10]. It was planned to include 40 subjects. The data of the previous study indicated that the difference in the response of matched pairs is normally distributed with a standard deviation of 200  $\mu\text{m}$ . If the true difference in the mean response of matched pairs is 100  $\mu\text{m}$ , it will be able to reject the null hypothesis that this response variable is zero with a probability (power) of 86.9%. The Type I error probability associated with this test was set to 0.05.

Patients were recruited at the UMSOD between January 2014 and August 2014, and subsequently included in the study. The

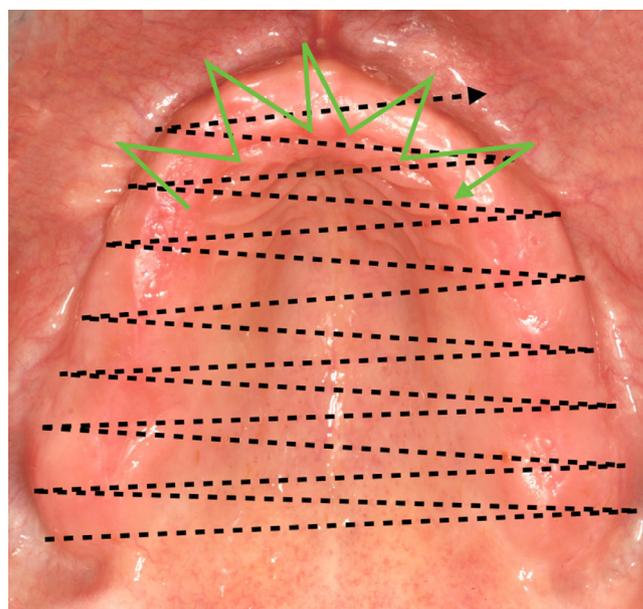


Fig. 1. Scan path in the maxillae. The black dotted line represents the primary scan path, the green line the additional anterior path.

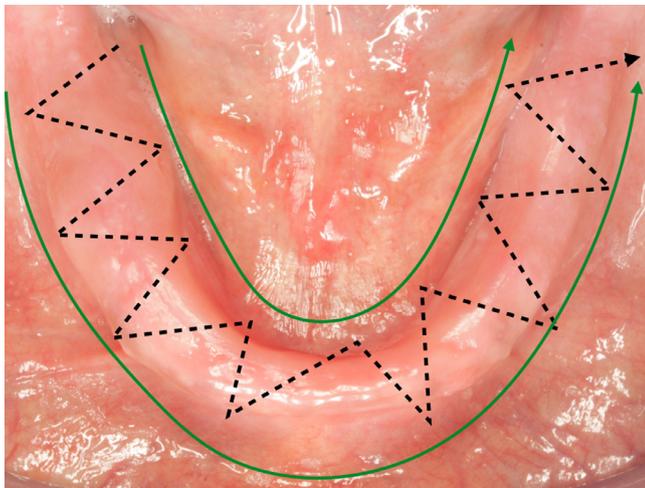
subjects were dental patients present for the treatment of edentulism by means of a complete denture for the upper and/or lower jaw/s. First, the patients were informed about the study objectives, potential risks, and compensations. Next, their eligibility regarding the inclusion criteria was checked and an informed consent had to be signed. The inclusion criteria were as follows: edentulism in the upper and/or lower jaws, no infectious diseases, age  $\geq 21$  years, healthy systemic conditions, and the patients had to be at the UMSOD for the treatment of edentulism. Exclusion criteria were as follows: presents of any teeth, inability to understand the objectives and procedures of the study, and refusal to sign the informed consent.

Customized trays were individualized in the region of the border seal zone with an impression compound Type I (Kerr, Orangeton, CA, USA), and conventional single mix vinyl-polysiloxane (Examix NDS monophase, GC America Inc., Alsip, IL, USA) impressions of the edentulous jaws were made. The impressions were made by prosthodontic faculty members and supervised students, finally checked by S.P. for correctness, digitized three times with a laboratory scanner (D700, Version 2013; Software: ScanIt Orthodontics 2012 and ScanIt Impression 2012, Version 5.4.0.7, 30/04/2013, 3shape, Copenhagen, Denmark), and poured with an ISO Type 3 stone (Micro stone gold, Whip Mix, Louisville, KY, USA). The stone casts were then scanned three times with the laboratory scanner (D700) as well.

At least one hour after the conventional impressions were made, three computerized optical impressions (COIs) per edentulous jaw were achieved with an intraoral scanner (Lava Chairside Oral Scanner, C.O.S. or True Definition Intraoral Scanner, 3M ESPE, St. Paul, MN, USA) following a specific scan path (Figs. 1 and 2). Dusting of the jaws was required with a Titanium oxide powder (High-Resolution Scanning Spray, 3M ESPE).

For the upper jaws, the digitization started at the region of the right tuberosity and continued with a zig-zag-wise path to the anterior region. Then, the scan was saved, and a scan of the anterior vestibule was taken. The scans were automatically aligned, fused, and saved. Missing areas were rescanned (Fig. 1).

The scans of the lower jaws started at the right retromolar pad area and followed the anatomy of the lower jaw in a zig-zag-wise path to the opposing site. The scans were saved, and additional



**Fig. 2.** Scan path in the mandibles. the black dotted line represents the primary path, the green line the additional scan paths of the labial, buccal and lingual vestibules.

scans of the vestibule and sublingual areas were added. Missing areas were rescanned (Fig. 2).

In total, nine surface scans were retrieved - three datasets per jaw of the conventional impression, three datasets of the stone cast, and three COIs. The datasets were loaded into 3D evaluation software (Geomagic Qualify 2013, Geomagic, Morrisville, NC, USA) and checked for deviations. For this, the datasets were evaluated for artifacts obviously not related to the actual surface of interest; they were cropped and aligned using the best-fit algorithm of the software. The aligned surface scans were then submitted for 3D comparisons. Of the three conventional impression scans and the three stone cast scans, one was picked each for the comparisons to the COIs. The obtained difference values were then statistically analyzed and visually evaluated.

### 3. Statistical analyses

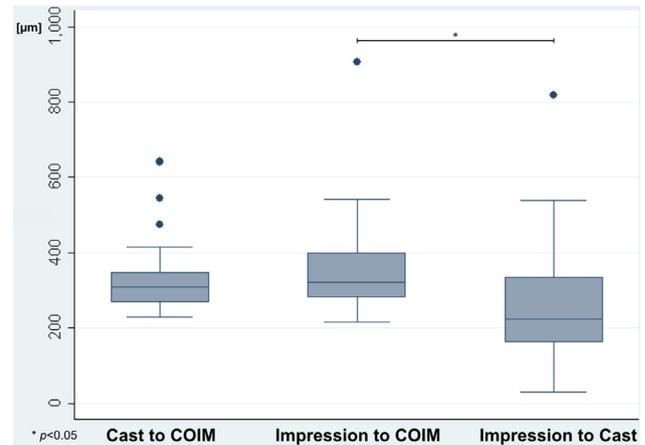
For descriptive analyses, the means, medians, standard deviations (SDs) and standard errors (SEs) were computed. Furthermore, boxplots were created for graphical presentation of the data. Linear mixed models with random intercepts for each patient were fitted to evaluate device and method (conventional impression, stone casts, COIM) effects on response variables. To take heteroskedasticity into account the error variances were allowed to differ between the methods. Subjects were considered as clusters, as several measurements (conventional impression, stone cast, COIM) per subject were accomplished. The method of “Scheffe” was applied to adjust the *p*-values due to the multiple testing problem when several pairwise comparisons are done. The calculations were performed with the statistical software STATA 13 (College Station, Texas, USA).

### 4. Results

#### 4.1. Statistical analyses

All results are given as mean values  $\pm$  standard deviation. If mean values are listed with their standard errors, (SE) is stated.

63 patients were screened for potential inclusion. Finally, 38 patients were preliminarily included and informed about the study. One patient had to be excluded due to a limited mouth opening, one refused to participate in the study without giving a reason, one patient did not show up for the COI, and one patient had to be withdrawn due to general health problems not related to the subject matter of the study. This resulted in 34 included patients



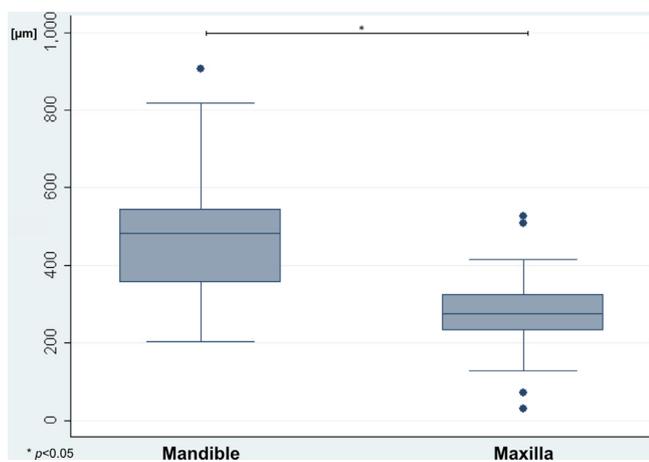
**Fig. 3.** Overall comparison of the three groups: ‘Cast to COIM’, ‘Impression to COIM’, and ‘Impression to Cast’. Asterisks (\*) mark statistically significant differences. COIM, computerized optical impression making.

of which 29 patients were available for the COIMs (27 maxillae, 5 mandibles). In total, 18 (21.2%) datasets of the Lava C.O.S. and 67 (78.8%) datasets of the 3 M True Definition Scanner were accessible for analyses. In a first comparison, it could be shown that there was not statistically significant difference between the scans obtained from the Lava C.O.S. (overall mean  $374.0 \pm 227.5 \mu\text{m}$ ) and the 3 M True Definition Scanner ( $308.4 \pm 109.4 \mu\text{m}$ ). An overall difference of  $66.6 \pm 49.0 \mu\text{m}$  (SE) was calculated ( $p = 0.216$ , 95% CI  $-162.4$  to  $29.3$ ). Therefore, in all further calculation no distinction between the Lava C.O.S. and the 3 M True Definition Scanner was made.

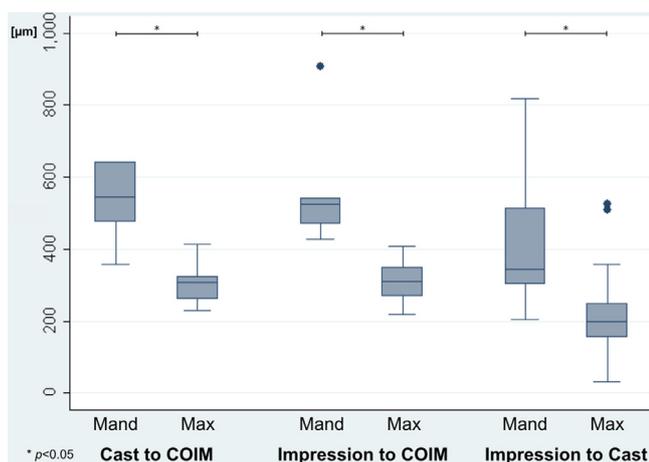
Further, it was checked to evaluate if there is a difference between the three comparison groups: ‘Cast to COIM’, ‘Impression to COIM’, and ‘Impression to Cast’. Here, it was not distinguished between maxillae and mandibles. The overall mean difference between the stone cast scans and COIM, the conventional impression scans and COIM, and the conventional impression and stone cast scans were  $336.7 \pm 105.0 \mu\text{m}$  ( $n = 32$ ),  $363.7 \pm 143.1 \mu\text{m}$  ( $n = 24$ ), and  $272.1 \pm 168.5 \mu\text{m}$  ( $n = 29$ ), respectively. A difference was detected between the ‘Cast to COIM’ and ‘Impression to Cast’ group ( $p = 0.088$ ) as well as a statistically significant difference between the ‘Impression to COIM’ and the ‘Impression to Cast’ group ( $p = 0.029$ ; Fig. 3).

The overall mean difference values for the mandibles were  $493.1 \pm 180.8 \mu\text{m}$  ( $n = 18$ ) and for the maxillae  $276.4 \pm 87.8 \mu\text{m}$  ( $n = 67$ ). Overall, there was a statistically significant difference between the mandibular and maxillary measurements of  $-216.5 \pm 29.9$  (SE)  $\mu\text{m}$  ( $p < 0.0001$ , 95% CI  $-275.1$  to  $-157.9$ ; Fig. 4). When distinguishing between mandibles and maxillae, the mean deviations in the groups ‘Cast to COIM’, ‘Impression to COIM’, and ‘Impression to Cast’ were  $574.4 \pm 191.4 \mu\text{m}$  ( $n = 5$ ) and  $300.4 \pm 46.9 \mu\text{m}$  ( $n = 27$ ),  $532.4 \pm 119$  ( $n = 5$ ) and  $308.3 \pm 50.6 \mu\text{m}$  ( $n = 19$ ), and  $417.8 \pm 194.7 \mu\text{m}$  ( $n = 8$ ) and  $216.6 \pm 121.6 \mu\text{m}$  ( $n = 21$ ), respectively. The statistically significant differences between the mandibles and maxillae were  $-232.0 \pm 29.1 \mu\text{m}$  (SE) ( $p = 0.000$ ; 95% CI  $-289.0$  to  $-174.9$ ),  $-266.1 \pm 45.0 \mu\text{m}$  (SE) ( $p < 0.0001$ ; 95% CI  $-354.4$  to  $-178.0$ ), and  $-201.131 \pm 57.8 \mu\text{m}$  (SE) ( $p = 0.003$ ; 95% CI  $-314.4$  to  $-87.9$ ; Fig. 5).

Distinguishing between the mandibles and the maxillae revealed no significant differences between the groups ‘Cast to COIM’, ‘Impression to COIM’, and ‘Impression to Cast’ for the mandibles (Fig. 6), however, for the maxilla there were statistically significant differences between the groups ‘Cast to COIM’ and ‘Impression to Cast’ ( $p = 0.001$ ), and between ‘Impression to COIM’ and ‘Impression to Cast’ ( $p = 0.001$ ) (Fig. 7).



**Fig. 4.** Overall comparisons of the differences between the mandibular and maxillary measurements showing a statistically significant difference (\*).



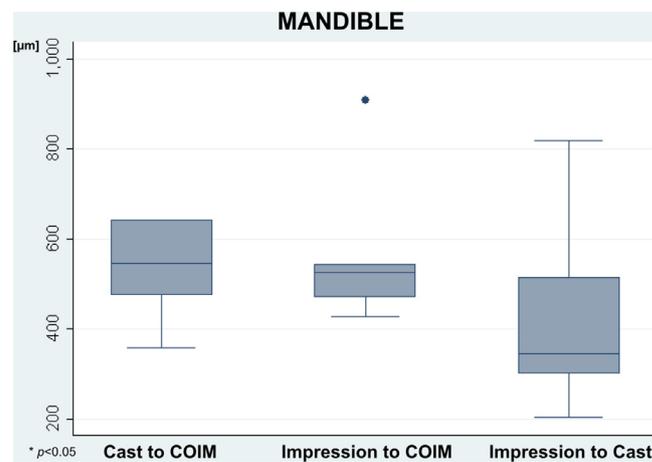
**Fig. 5.** Comparisons of all three groups showing statistically significant differences between mandibles and maxillae. Asterisks (\*) represent statistically significant differences. Mand, mandible; Max, maxilla; COIM, computerized optical impression making.

#### 4.2. Visual evaluation of the maxillae

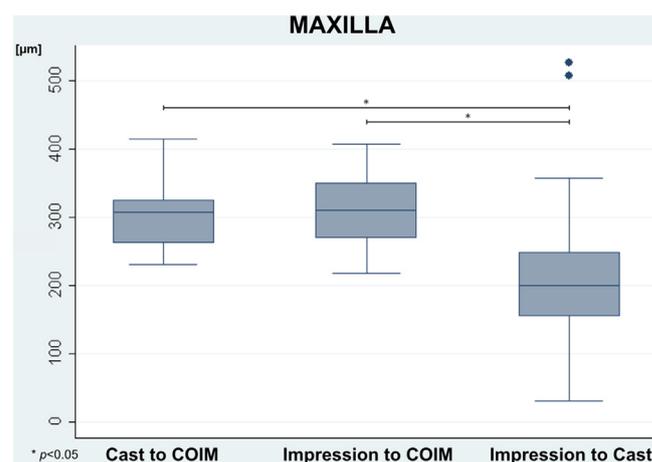
The visual evaluation of the superimposed and color-coded comparisons of the maxillae revealed the highest deviations ( $\geq 500 \mu\text{m}$ ) in the areas of the soft palate and the vestibule (peripheral seal zone). Additionally, most un-captured data were located in the regions of the maxillary tuberosities, as well as the mobile tissue of the vestibule. Small deviations ( $0\text{--}100 \mu\text{m}$ ) were identified in areas of the attached gingiva. The superimposed datasets of the stone casts (Fig. 8) and the conventional impressions (Fig. 9) compared to the COIM datasets revealed these findings consistently. The superimposition of the conventional impressions to the stone casts, however, did not show in general any patterns of deviations in specific regions (Fig. 10). These comparisons usually evidenced homogeneous deviations.

#### 4.3. Visual evaluations of the mandibles

The color-coded superimposition of the mandibular datasets revealed the highest deviations ( $\geq 500 \mu\text{m}$ ) in the sublingual areas and the vestibule. Missing areas were predominately located in the retromolar pad areas, the vestibule and the sublingual region – all associated with areas of mobile tissue. The identified deviations occurred in the ‘cast to COIM’ (Fig. 11) and ‘impression to COIM’



**Fig. 6.** Comparisons of the mean deviations of the groups ‘Cast to COIM’, ‘Impression to COIM’ and ‘Impression to Cast’. COIM, computerized optical impression making.



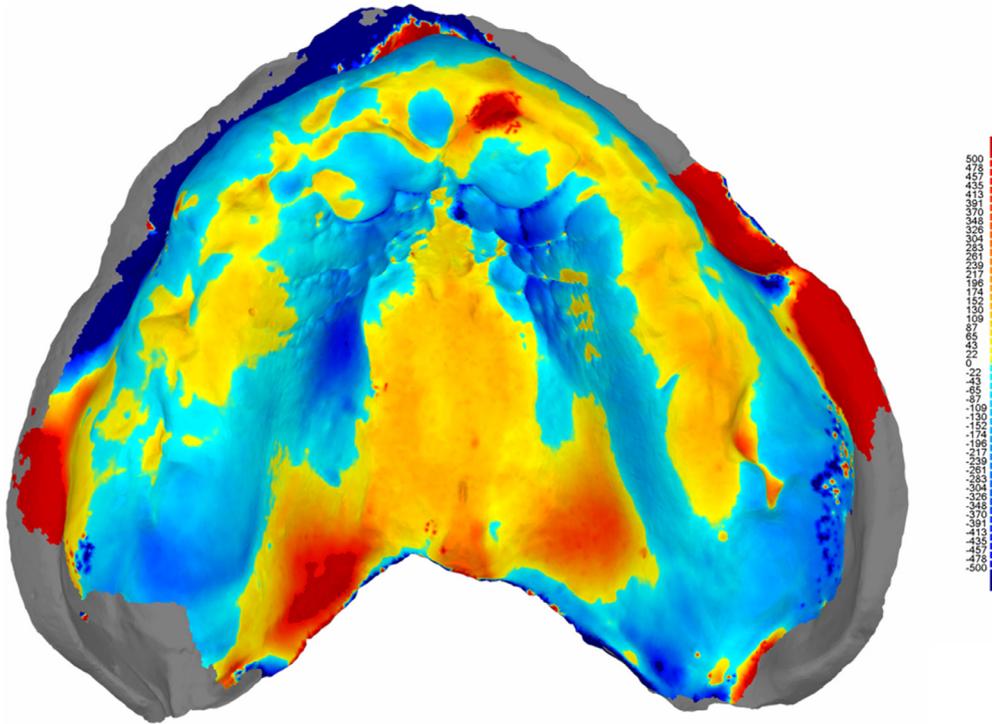
**Fig. 7.** Comparisons of the mean deviations of the groups ‘Cast to COIM’, ‘Impression to COIM’ and ‘Impression to Cast’. Asterisks (\*) represent statistically significant differences. COIM, computerized optical impression making.

(Fig. 12) groups. Similar to the maxilla, the comparisons of the impressions to the casts revealed smaller, homogeneous deviations (Fig. 13).

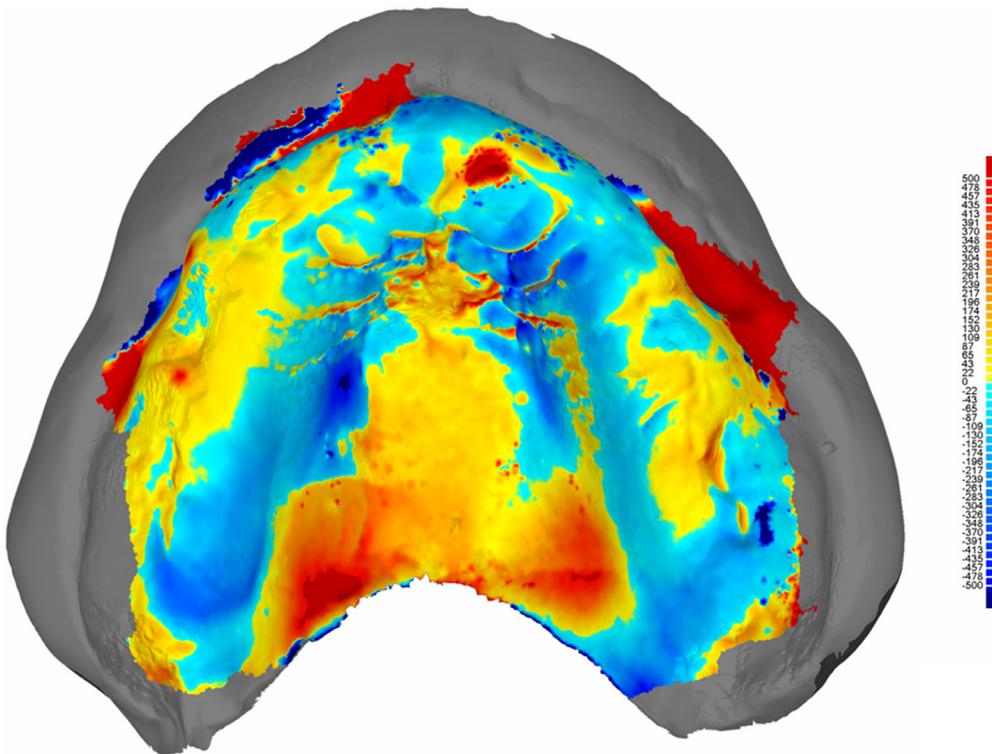
## 5. Discussion

The present study was designed as a prospective controlled clinical study to investigate the feasibility of computerized optical impression making of entirely edentulous jaws. Additionally, differences between optical surface scans of conventional impressions, stone casts, and COIs were evaluated. The null hypothesis that there are no differences between conventional impressions, stone casts and COIs have to be rejected. COIs of edentulous jaws do not result in the same surface information as obtained from conventional impressions and the resulting stone casts.

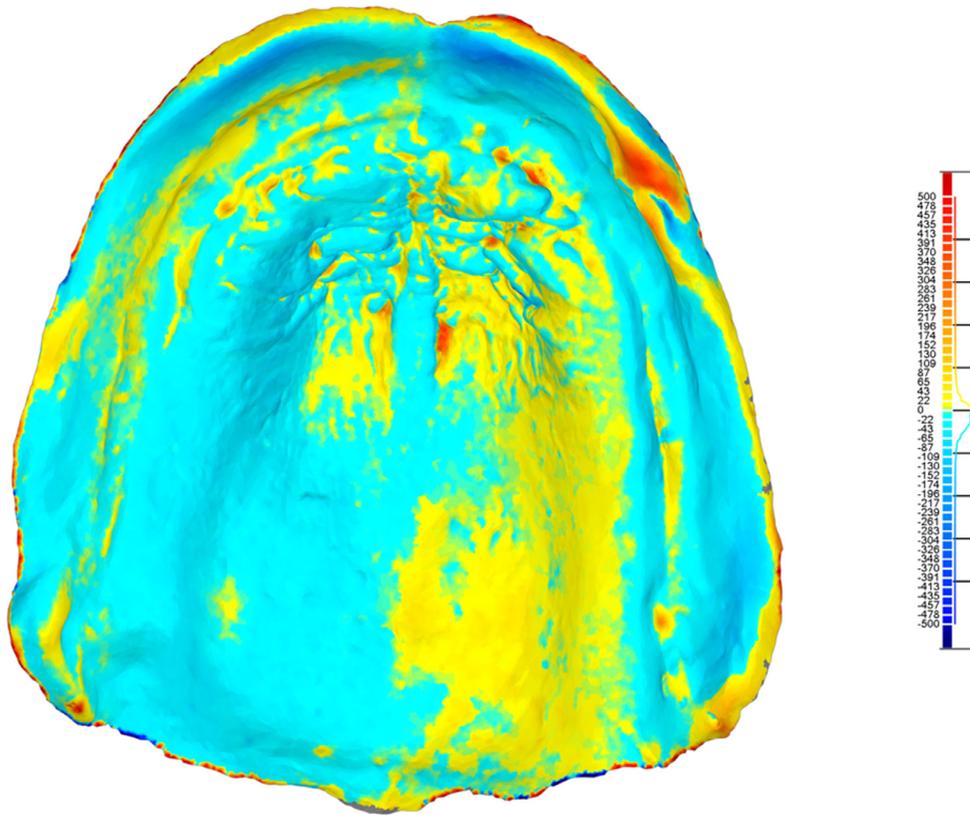
Following a sample size calculation, edentulous patients at the UMSOD were recruited. Most of the patients (89.5%) were treated for edentulism in the prosthodontic student courses. Four patients (10.5%) received their treatment from dental professionals. This did not affect the COIM, however, it might have affected the conventional procedures (impressions and stone casts). Further, it has to be taken into account when interpreting the results of the present study that only five patients were available for computerized optical impressions of edentulous mandibles.



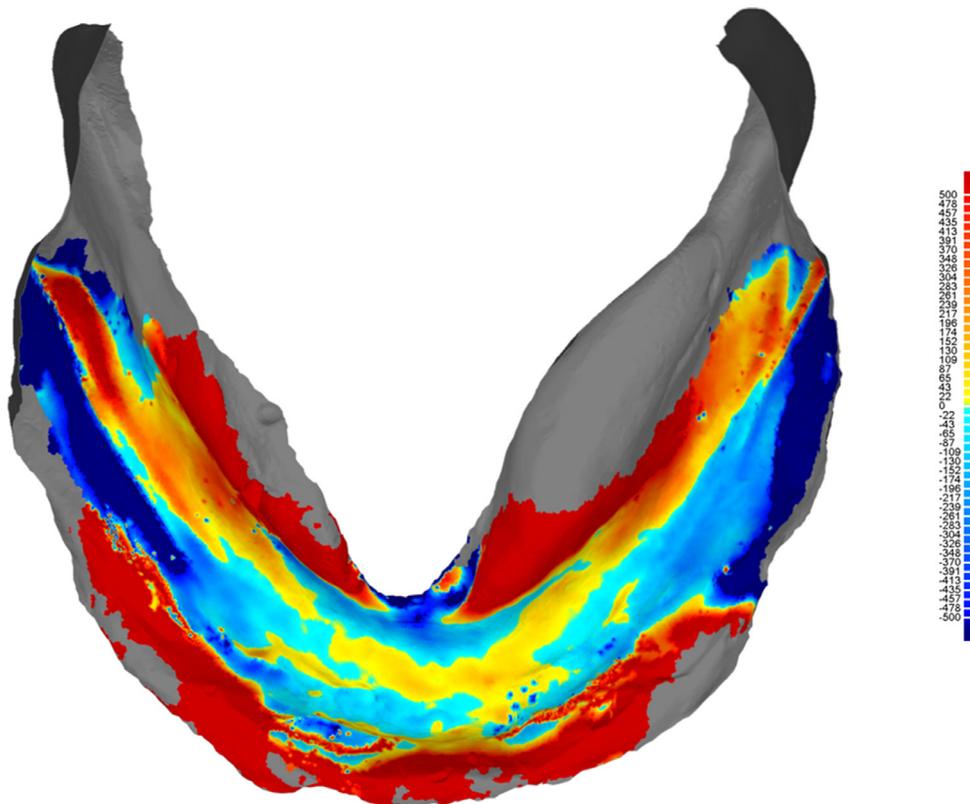
**Fig. 8.** Exemplary color-coded ( $\mu\text{m}$ ) image of a maxillary stone cast to COIM comparison showing highest deviations and missing data (gray areas) in the areas of the soft palate and vestibule. COIM, computerized optical impression making.



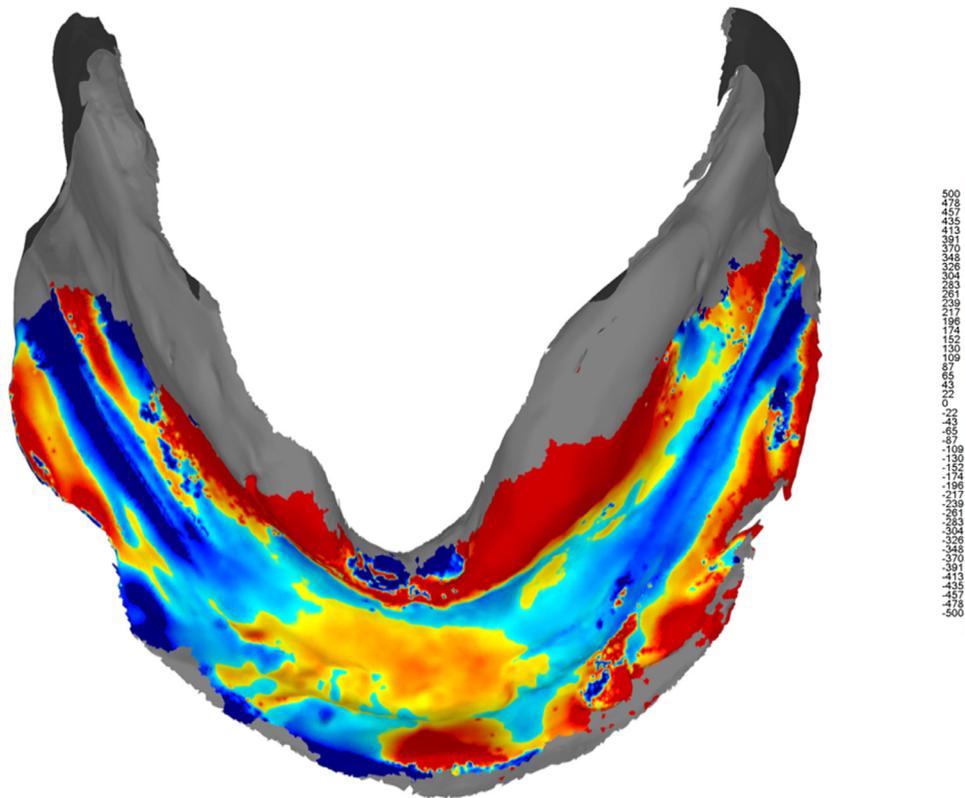
**Fig. 9.** Exemplary color-coded ( $\mu\text{m}$ ) image of a maxillary conventional impression to COIM comparison showing highest deviations and missing data (gray areas) in the areas of the soft palate and vestibule. COIM, computerized optical impression making.



**Fig. 10.** Exemplary color-coded ( $\mu\text{m}$ ) image of a maxillary conventional impression to cast comparison showing highest deviations and missing data (gray areas) in the areas of the soft palate and vestibule. COIM, computerized optical impression making.



**Fig. 11.** Exemplary color-coded ( $\mu\text{m}$ ) image of a mandibular stone cast to COIM comparison showing highest deviations and missing data (gray areas) in the sublingual areas, the vestibule, and areas of mobile tissue. COIM, computerized optical impression making.

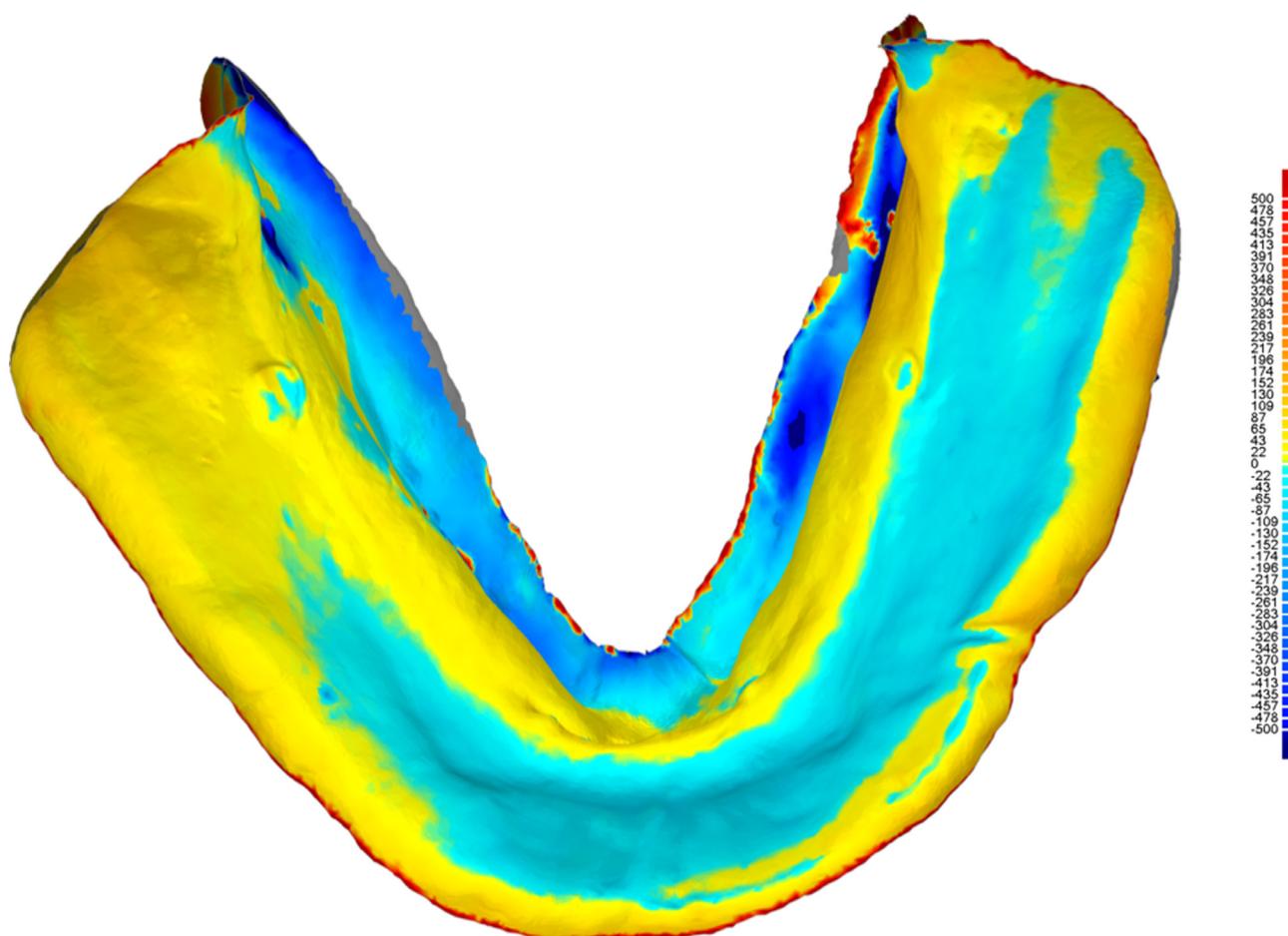


**Fig. 12.** Exemplary color-coded ( $\mu\text{m}$ ) image of a mandibular conventional impression to COIM comparison showing highest deviations and missing data (gray areas) in the sublingual areas, the vestibule, and areas of mobile tissue. COIM, computerized optical impression making.

Making a conventional impression of edentulous jaws can be one of the most challenging procedures in dentistry [40–43]. Especially, areas of mobile tissue such as the vestibule in the maxilla and mandible as well as the sublingual areas in mandibles are of high interest [44–49]. These areas are called peripheral seal zone, this is the contact area of the complete denture border with the underlying or adjacent tissues to prevent the passage of air or other substances [1], and is essential for the suction effect, and thus for the retention of complete dentures [50]. To get a sufficient impression of the peripheral seal zone significant efforts are made to capture this mobile structure. A customized impression tray is used for the ridge impression combined with an individual border molding technique [51–53]. When border molding, the material is consecutively added to the borders of the custom tray thus creating a patient specific preliminary impression of the vestibule. This is the most critical step of impression making of edentulous jaws, and as previously mentioned, essential for the final retention of the denture. In this study, a high quality of this step according to prosthodontic principles was guaranteed by double-checking the border molding – first by the student him-/herself, second by a prosthodontic faculty, and third by the principle investigator (S.P.). Nevertheless, having done the impressions by only one experienced investigator might have resulted in different outcomes since potential inter-individual experiences and skills could not be eliminated. This should be considered when interpreting the results of the present study and in the design of future study.

Generally, a variety of conventional impression materials are available. In edentulous cases gypsum, composite materials, alginate, silicones, zinc-oxide-eugenol, autoplactic acrylic materials, wax resins, gutta-percha, and soft reline materials are named [54]. Nowadays, silicones and zinc-oxide-eugenol are predominantly used, due to their superior processing (cartridge systems, adaptable working time) and patient comfort characteristics (taste,

setting time, removal). In the present study, a vinyl-polysiloxane (VPS) was used. This impression material offered a straightforward processing, and a sufficient dimensional stability (recovery from deformation 99.5%, maximum strain in compression  $\leq 3.3\%$ , linear dimensional change after 24 h  $\leq 0.2\%$ ; (GC America Inc. [55]). For the subsequent fabrication of the stone casts, an ISO Type 3 stone was used for pouring the VPS impressions. This specifically designed stone for the fabrication of acrylic dentures exhibits an expansion of 0.14%, and a compressive strength of 59 MPa after 48 h. Considering the dimensional change of the impression material and the expansion of the stone, there is, depending on the material properties, a distortion of around 0.35% [56]. Usually, the impression material exhibits shrinkage, which is compensated by the expansion of the stone. Therefore, in the present study the deviation from the real intraoral situation of the conventional workflow (VPS impression + stone cast) amounted to 0.06%, when considering only the material-related dimensional changes. The dimension of a regular stone cast is approximately  $6 \times 6 \times 3$  cm. This results in a distortion of  $3.6 \times 3.6 \times 1.8 \mu\text{m}$  (volumetric deviation approx.  $23 \mu\text{m}$ ). Besides the material-related factors, patient- and dentist-related factors can influence the dimensional accuracy of the impression as well. Anatomical factors like the amount of attached gingiva, the depth of the vestibule, and the resilience of the soft tissue significantly influence the quality of the impression, and thus the fit of a complete denture. Missing attached gingiva, associated with a flat vestibule, render a proper impression virtually impossible. The soft tissue resilience differs from the maxilla to the mandible. Usually, the resilience is higher in the maxilla. To avoid any displacement of the soft tissue, impression materials with low viscosities have been previously used [57,58]. From this perspective, COIM could be generally beneficial, since the optical radiation has no displacing effect on the tissue.



**Fig. 13.** Exemplary color-coded ( $\mu\text{m}$ ) image of a mandibular conventional impression to cast comparison showing highest deviations and missing data (gray areas) in the sublingual areas, the vestibule, and areas of mobile tissue. COIM, computerized optical impression making.

Based on results of a previous *in vitro* study [10] identifying the Lava C.O.S. as COIM system of choice when it comes to digitizing edentulous jaws, the mentioned scanner and its successor were chosen for the present study. Both systems utilize an active wave front and video technology capturing 20 images per second. Video-based systems with image capturing rates  $> 20$  Hz seems to be beneficial for capturing smooth surfaces, as it is the case in edentulous jaws. The present technology requires a light dusting of the soft tissue surfaces to be captured. However, it was sometimes challenging to maintain the coating the powder. Saliva and the tongue movement lead to some removal of the powder, requiring a re-dusting after each scan or even during scanning. From this perspective, powder-free systems might be beneficial. Further, it is not clear whether the powder has a negative effect on the accuracy, or even adverse health effects when inhaling the particles (particle size approx.  $20 \mu\text{m}$ ). This needs to be investigated in future studies.

Based on the results of Patzelt et al. [10], and the fact that there is no recommendation from the manufactures on how to scan edentulous jaws, a zig-zag-wise scan path was identified to be the most useful to obtain closed surface data. Following this pattern, it was possible to maintain sufficient overlapping and capturing of adjacent structures. Ender and Mehl [59] were able to show that the scan strategy or path has a significant influence on the accuracy in terms of trueness and precision. However, they investigated dentated jaws in their previous study. Nevertheless, the same effect can be expected when scanning edentulous jaws. However, it was not investigated whether a different strategy would have

revealed different results. Moreover, it was observed that when not being able to follow the zig-zag path, it was not possible to generate a sufficient dataset. To statistically minimize the influence of the scan path, three scans per jaw were taken and evaluated.

As for all *in vivo* investigations related to computerized optical impression making, it is not possible to compare the optical scan to a highly accurate scan of the actual jaw with a device of known accuracy. Since for this purpose, the jaw needs to be scanned with a laboratory device, which is technically not possible. Therefore, in the present study, the computerized optical impressions were compared to the gold standard – the conventional impression/stone cast. Thus, the present investigation represents a comparative study of two different methods of obtaining surface information. It is not possible to give a conclusion on the real accuracy, since as above mentioned, even the gold standard exhibits a deviation to the real situation. Nevertheless, the present method was a valid approach to reveal limitations of an emerging technology, and to provide recommendations to clinicians.

The comparisons of the surface scans revealed significant differences between the mandibles and maxillae, as well as between the conventional impressions/casts and the COIM approach. The mean deviations in the groups 'Cast to COIM' and 'Impression to COIM' in the mandible were  $530$  and  $300 \mu\text{m}$ , and in the maxilla  $310$  and  $420 \mu\text{m}$ . Deviations up to  $0.5$  mm can be considered as too high for the fabrication of a complete denture. The visual evaluation revealed highest deviations and missing parts in the areas of mobile tissues, such as the vestibule and the sublingual areas. Whereas prosthodontic textbooks emphasize the importance

of these areas as essential for the retention of complete denture, Lo Russo et al. stated that according to the mucostatic impression concept, denture retention is established by the surface tension between the complete denture and the tissue, and not by the peripheral seal [60]. Thus, they reported a sufficient COI (Trios 3 color, 3Shape, Copenhagen, Denmark) of an edentulous maxilla and fabrication of a complete denture with a digital CAD/CAM workflow. Possible in an *in vitro* study by Patzelt et al. [10], in the present study, it was not possible to capture all characteristics of the edentulous jaws relevant for the fabrication of a complete denture. Especially, the scanner was not able to capture areas of highly mobile tissue such as the oral vestibule (peripheral seal zone) or sublingual areas. This is related to specific software implementations that delete automatically areas not steady over time. Current intraoral scanners focus on capturing hard tissues and immobile areas thus the software algorithm removes automatically scans of the tongue, the vestibule, mobile areas of the palate as well as dental mirrors, fingers or the suction. In some cases, where a steady vestibule could be established, it was even possible to capture the peripheral seal zone in some areas. Nevertheless, areas of the attached gingiva (alveolar ridge, hard palate) could be captured sufficiently suggesting an application of the investigated scanner in scenarios where mobile tissue is of lower relevance (implant-supported restorations).

A search for literature focusing on the subject matter of the present investigation revealed five publications [10,26,60–62], however, none of them evaluated the integrity of the retrieved digital data in an *in vivo* setting. Patzelt et al. [10] investigated the feasibility and the accuracy of scanning edentulous jaws in an *in vitro* setting. They digitized one upper and one lower study model with four intraoral scanners (CEREC AC with Bluecam [Sirona, Bensheim, Germany]; Zfx IntraScan [manufactured by MHT Italy, Negrar, Italy/ MHT Optic Research, Niederhasli, Switzerland; distributed by Zfx, Dachau, Germany]; Lava Chairside Oral Scanner C.O.S. [3M ESPE, St. Paul, USA]; iTero [Align Technology, San Jose, USA]) and with an industrial reference scanner. They were able to identify similar deviations (mean absolute trueness up to 600 µm) with significant differences between the scanners. Highest deviations were found in areas with poorly traceable structures; however, the vestibule (peripheral seal zone) was captured sufficiently, due to the fact that no mobility was simulated.

Two case reports [26,60] by Lo Russo et al. and Kim et al. reported a sufficient possibility of digitizing an edentulous jaw and produce complete dentures based on the retrieved surface data. However, the periphery seal zone was only partially present. Lee et al. and Fang et al. [61–63] described techniques for digitizing edentulous jaws without any interpretation of the retrieved data.

Beside these studies, there are numerous publications reporting on the CAD/CAM fabrication of complete dentures [11–32,34–38,64–67]. Based on surface data obtained from digitized conventional impressions or casts in combination with a scan of the intraoral jaw registration, a digital design of a complete denture is possible. This data can be transferred to a milling machine or additive technology for fabrication of the denture. The missing link to establish an entirely digital workflow is the initial step of making the impression. As shown in the present investigation, the investigated scanners were not able to replace the conventional impressions in all aspects, especially when it comes to the digitization of mobile tissue such as the peripheral seal zone.

Future studies should focus on technical developments enabling optical scanners to capture the critical areas of mobile tissue. These technical developments might be related to the sensors such as sensor size, pixel size and number, and capturing rate, as well as to software-related issues such as the ability to double or triple scan areas and align and merge them to create a single master digital model out of several scans. Further, a method for the digital de-

sign of the denture needs to be developed that is able to capture the vertical and horizontal jaw relation as well as the characteristics of the lip and aesthetics.

## 6. Conclusion

Within the limitations of the present study, the investigated scanners are not able to adequately capture mobile and poorly traceable tissues. Technical and software-related improvements are necessary to be able to capture mobile soft tissue sufficiently. Nevertheless, using the investigated scanners for capturing edentulous arches for restorations other than complete dentures seems to be possible. Future studies need to investigate whether the latest generation of optical scanners has overcome the existing limitations.

## Declaration of Competing Interest

The authors declare that there is no conflict of interest.

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