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# Accuracy of Intraoral Scanners for Recording the Denture Bearing Areas: A Systematic Review

Running title: Intraoral Scanner Accuracy In Denture Bearing Area

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Abstract

**Purpose**: To systematically review clinical and laboratory studies that investigated the accuracy of intraoral scanners in recording denture bearing areas.

**Materials and Methods:** Electronic and manual searches were conducted to identify all the available clinical and laboratory studies reporting the accuracy of digital impressions for recording denture related soft tissues. After the application of predetermined inclusion and exclusion criteria, the final list of articles was reviewed to meet the objective of this study.

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**Results:** The inclusion criteria were met by 18 studies out of which 8 were clinical and the rest were laboratory investigations. The eligible studies assessed the accuracy of intraoral scanners in recording both the denture supporting structures and the peripheral mobile tissues. The accuracy results were different among the various intraoral scanners. Likewise, the effect of several influencing factors, such as artificial markers, scanner head size, scanning strategy, and the operator's experience, were evaluated.

**Conclusion:** While the accuracy of intraoral scanners was comparable to the conventional techniques in recording bony structures with attached mucosa, they were not capable of accurately registering the mobile tissues. In addition, factors such as presence of a marker, larger scanner head size and specific scanning techniques appeared to improve the accuracy of the digital impression.

**Keywords:** Direct digital impression, removable prosthesis, optical scanner, trueness, precision

Several impression materials and methods have been advocated for the definitive impression in removable prosthodontics. While a long track record of proven accuracy is available for the conventional methods,[1] the accurate result still demands careful material handling. The potential errors throughout the procedure, such as excessive or insufficient pressure during impression making, improper sterilization procedure, mechanical undercut and elastic deformation, could affect the accuracy of the definitive impression.[2,3] Additionally, the innate material limitations, including volumetric changes of the impression material and the stone model, are inevitable.[4] The advent of direct digital impression has eliminated many of these shortcomings. Further, it improves the communication between the patient, clinician, and dental laboratory. Real-time visualization provides the benefit of immediate evaluation of the impression adequacy. Permanent storage of the data, ease of transfer, and reduced patient discomfort during impression making are clear advantages of the digital impression over the conventional methods.[5] The majority of the studies that investigated the accuracy of intraoral scanners (IOS) focused on capturing the teeth and implants with promising outcomes.[6,7]

In recent years, there has been an increased interest in digital removable dentures. Although the current concepts of digital dentures prominently involve the laboratory procedures,[8,9] integration of the IOS in the workflow provides the opportunity for full digitization of denture fabrication. However, there are challenges around the direct digital impression of edentulous jaws. Oral mucosa represents a smooth translucent surface with simple geometry that is covered entirely by saliva. Such characteristics could raise cumulative errors in the stitching process.[10] Additionally, there are clinical difficulties in recording functional depth and width of sulci, access to the posterior areas,[7] and the inability to record the tissues under selective pressure.[11] While some authors reported the feasibility of direct digital impressions as the definitive imprint of edentulous jaws,[12,13] a question remains as to how accurate the IOSs are in recording the denture bearing areas. The present systematic review aimed to investigate the accuracy of IOS in recording the denture-related mucosa.

## Materials and methods

This systematic review was based on the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA). The PICO framework was used to form the following search strategy: Population: denture bearing area and soft tissue, Intervention: IOS technique, Comparison: a reference model/ alternative impression techniques, Outcome: accuracy.

### Search strategy

The main formulated search strategy was performed in the PubMed (MEDLINE) database (Table 1). Additionally, individual search strategies were developed using the main search as the reference and applied in the EMBASE, Scopus, and Cochrane Central Register of Controlled Trials databases. The searches were conducted in October 2020 and updated in November 2020. A reference manager software program (Endnote X9, Clarivate Analytics, Philadelphia, PA) was used to eliminate duplicate articles from different searches.

With regard to inclusion criteria, clinical and laboratory studies with control groups that investigated the accuracy of IOS for scanning denture bearing soft tissue and written in English language were included. Conversely, reviews, letters, case reports/series, studies in which merely the dental arch or implant component scanning were involved, or scanned the soft tissue other than the denture bearing area, or studies in which the accuracy could not be determined, or involved fit evaluation of the prosthesis, were not considered for analysis.

### Selection of studies

Two independent reviewers (V.R., S.H.) participated from the first phase of study selection by choosing articles based on the information provided in the title and abstracts. Following this, abstracts of all titles, agreed on by both investigators, were obtained for full-text analysis and matching against inclusion criteria. In case of disagreement, a third reviewer (J.A.) was consulted. Finally, articles considered eligible for review were selected. Further, a supplemental hand search was conducted through the reference lists of the included studies. The risk of bias assessment was performed by the Quality Assessment tool for Diagnostic Accuracy Studies (QUADAS).[15] Only relevant questions to the eligible studies were selected for scoring (n =13) (Table 2). “Yes” answers scored 1 and “no” or “unclear” answers scored 0. The highest score (13) indicated lower risk of bias.

## Results

A total of 315 articles were obtained from the initial electronic search, which was reduced to 286 after removing the duplicate reports. Subsequent to study selection based on title and abstract relevance, 37 articles were identified to be analyzed by full-text. After the implementation of the exclusion criteria, 18 articles were identified to be eligible for final reporting. The supplemental hand search did not result in any additional articles (Figure 1). According to the investigated denture bearing area, the eligible studies were organized in 4 groups: completely edentulous arch studies, partially edentulous arch studies, completely and partially edentulous arch studies, and palatal area studies.

**Accuracy variables and evaluation methods**

The accuracy data were extracted from the included articles. The following methods were implemented by the studies:

a) Dimensional measurement: Out of the 18 studies that satisfied the inclusion criteria, 1 measured the distance between markers on a physical model and compared it to the distance between the similar markers on its virtual counterpart produced by the IOS.[16]

b) Superimposition accuracy: The superimposition accuracy was based on the definition of accuracy by ISO-5725-1,[17] which is determined by trueness and precision. Trueness is defined as the closeness of the test object to the actual reference object, and precision represents the similarity between the different test objects. From the 18 studies, 17 of them used the superimposition method to measure the congruence between the reference and the test group 3D data (trueness) and/or the congruence of the 3D data within each test group (precision).[18-34] To do so, 11 studies obtained the reference 3D data through a laboratory scanner,[18,19,21,25-32] 3 used an industrial scanner,[20,22,34] and 1 used the same IOS employed to capture the direct digital impression.[23] The virtual models were superimposed using the best fit algorithm of a 3D software. To measure the accuracy, the discrepancy between the models were quantified. The less the value, the greater the accuracy.

c) Qualitative evaluation: Out of the 17 studies that used the superimposition method, 14 described the pattern of the positive and negative differences between the IOS-generated virtual model and the reference 3D data by visualizing through a color map.[18,20-25,27-30,32-34]

**Completely edentulous arch studies**

A total of 9 articles evaluated the accuracy of IOSs in completely edentulous arches (Table 3).[16,21,23,25,27,29,32-34] Five studies were clinical experiments[23,25,27,29,32] and 4 were laboratory investigations.[16,21] None of the clinical studies included participants with severe bony undercuts or severely resorbed residual ridges. The majority of the studies included accuracy evaluation of Trios 3 (TR3) (3Shape) (n = 6).[16,23,25,32-34] This was followed by iTero (IT) (Align Technology) (n=2),[16,21] Lava C.O.S (LC) (3M ESPE) (n=2),[21,29] True Definition (TD) (3M ESPE) (n=2),[29,33] Cerec Bluecam (CB)/ Cerec Omnicam (CO) (Dentsply Sirona) (n=1+2),[16,21,33] Planmeca Emerald (PE) (Planmeca) (n=2),[16,33] CS3500 /CS3600 (Carestream) (n=1+1),[16,27] Zfx Intrascan (ZFX) (MHT Italy) (n=1),[21] Straumann Cares IOS (DW) (Straumann ) (n=1),[33] and Aadva iOS100 (AD) (GC) (n=1).[33] Four studies evaluated more than one IOS.[16,21,29,33]

The dimensional measurement study calculated the distance between 5 markers distributed over an edentulous mandibular arch. The measurements were evaluated in the short arch (pairwise comparison between markers) and complete arch (cross-arch comparison between markers) patterns. Five different IOSs (CO, IT, PE, CS3600, TR3) were used in the study. For the complete arch measurements on the edentulous scan, PE and CO were shown to have the lowest and highest trueness values, respectively. The short arch measurements revealed the lowest trueness values for IT and the highest for CS3600. The study reported a clear effect of the scan distance on the 3D data accuracy, where the greater scan distance is associated with more errors.[16]

In a laboratory study, Patzelt et al. reported significantly different levels of accuracy by various IOSs (CB, IT, LC, ZFX). They found the smallest and most consistent distance errors for the LC, and the largest and least consistent for the CB. The accuracy of scans was not different in the maxilla and the mandible. According to the qualitative evaluations, the highest deviations and digital mismatches were reported in the palatal region. However, the vestibular areas were captured sufficiently, due to the fact that no mobility was simulated.[21] The clinical studies investigated the accuracy of intraoral scanners in recording both the denture supporting tissues and the denture peripheral seal zone.[23,25,29,32] D'Arienzo et al. reported a difference of more than 500 µm in only 10% of the scanned maxillary arches in comparison to the stone models. The color map analysis revealed deviations particularly in the soft palate, buccal and labial vestibule.[25] Jung et al. limited the evaluation of the IOS accuracy to the denture supporting area in both edentulous jaws. The vestibular tissue was excluded from the data analysis due to its extreme mobility. The comparison of the mean differences between the IOS and the stone model revealed more congruence in the mandible rather than the maxilla. Although not statistically significant, the soft palate showed the greatest distortion. A difference of 300 µm was described as the acceptable threshold value. Based on this, the IOS accuracy in recording denture supporting areas in both arches was considered satisfactory.[27] In the same study, the qualitative evaluations revealed more pressed tissue in the posterior area for the IOS. Chebib et al. evaluated both the mobile and attached denture relevant mucosa in maxilla. They reported that the peripheral border was either missing or difficult to interpret in the direct scans. Thus, they found inferior peripheral border trueness compared to the polyvinyl siloxane (PVS) and zinc oxide eugenol (ZOE)-relined PVS impressions. The impression of bony structures (residual ridge and midpalatal suture), as well as posterior palatal seal area, was recorded adequately by all impression techniques with no meaningful differences. Analysis of the color map data showed almost half of the peripheral borders with positive (overextended sulci) and the other half with negative (underextended sulci) errors.[32] Lo Russo et al. found an improvement in trueness of digital scans by 10 fold when the mobile peripherial tissues were cropped from the full scans of the edentulous maxilla and mandible. However, the mean distance between the 3D data obtained from polysulfide impression and IOS was still significantly different after trimming scans of the maxilla.[23] Hack et al. found deviations of ≥500 µm in the soft palate, sublingual, and vestibular areas. Likewise, most uncaptured data reported were in the maxillary tuberosity and the mobile tissues. Conversely, small deviations were reported in areas with attached mucosa (alveolar ridge and hard palate). Significantly better accuracy was reported for the maxillary scans. Greater differences were found when the IOS-generated data were compared to the impression rather than the stone model. Moreover, no statistically significant difference was identified between the scans obtained from the two scanners used in the study (LC and TD).[29]

Osnes et al. investigated the precision of 6 different IOSs (TD, PE, CO, DW, TR3, AD) using the following two measures in vitro. The mean deviations over the full surface and the unsigned median error over the poorest 1% of the surface (upper-bound deviation), was measured to determine whether this data was likely to be scanner noise or true error with great clinical relevance. The largest mean deviation was associated with DW and PE, while AD displayed the lowest and most consistent values. However, all the error values were below 100 µm. On the other hand, the upper-bound deviations for PE and DW exceeded the 300 µm, which was designated as the clinically relevant threshold value. TR3, AD, CO, and TD all produced clinically acceptable scans according to both measures. Additionally, the study reported that much less than the greatest 0.5% of the data appeared to be spurious.[33] Zarone et al. evaluated the influence of the palatal irregularities (rugae) and the scanning strategy on the accuracy of IOS. Similar maxillary models with different surface irregularities (wrinkled and smooth) were scanned with three different scanning paths including the palatobuccal technique (PB), The S-shape technique (SS), and the buccopalatal technique (BP).

They reported no significant effect of the scanning strategy in the smooth model. However, the wrinkled model was digitized more accurately with BP technique. The overall results revealed higher accuracy for smooth model which was attributed to the software calculation method. In this regard, the software calculated the SD value of the global displacement between the whole superimposed surfaces. For this reason, the calculated mean value of errors was influenced by the area of the palatal rugae. The qualitative analysis showed outward and inward displacements with values less than 400 µm at the palatal region, buccal vestibule, and posterior peripheral borders.[34]

**Partially edentulous arch studies**

A total of 3 laboratory studies evaluated the IOS accuracy in the partially edentulous arches (Table 4).[24,26,28] All of the studies evaluated CS3500 and CS3600 (n=2+1).[24,26,28] The accuracy of CO,[26] TR3,[26] and i500 (Medit)[24] were investigated as well. Two studies evaluated more than one IOS.[24,26] Kim et al. used an external object to add a feature on a tooth-borne edentulous span. Unlike the trueness, presence of the marker showed a significant impact on improving the precision of the obtained 3D data. The study reported a significant influence of the type of scanner on the precision, whether the marker was present or not. In this regard, TR3 showed better results than CS3500. The CO was excluded from the analysis as there were registration problems in the absence of the marker. Moreover, they showed that the presence of an artificial marker reduced the scanning time due to fewer errors in the recording process. However, according to the increased number of captured images, the software calculation time and hence the total impression procedure increased compared to the time without the marker in place.[26] On stone model, Hayama et al.compared the accuracy of the conventional method and IOS with different scanner head sizes in the partially edentulous mandible. They found significantly superior trueness for the large IOS head in the full arch scan and solely mucosal area evaluations. While this finding was true for both the Kennedy class I and III mandibular models, the small head size showed significantly better trueness than the conventional method only in the mucosal area of the class III model. Conversely, for both IOS head sizes, precision was inferior to the conventional method. Comparison of the two scanner head sizes revealed better trueness and precision for the large IOS head with significantly fewer numbers of the scanned image for the full arch scan.[28] Lee et al. found that the length and distribution of missing teeth in the partially edentulous arch can affect the accuracy of the full arch digital scan. In this sense, inferior precision was reported with an increase in the number of missing teeth. This was irrespective of the type of IOS (CS3600 and i500). [24]

**Completely and partially edentulous arch studies**

A total of 2 laboratory studies evaluated the accuracy of digital scans in partially and fully edentulous arches in comparison to reference models (Table 5).[19,20] Tasaka et al. investigated the trueness of TR2 scans in certain areas of an edentulous maxilla and a partially edentulous mandibular model during the evaluation of the inter-operator validity. Their results revealed a significant inter-operator difference in the maxilla only. Although the overall results indicated satisfactory trueness, the longer free end in the mandible and the palatal area showed greater deviations.[19] The other study showed a significant influence of the type of edentulism and the operator's experience on the scan time, trueness, and precision. Completely and partially edentulous maxillary and mandibular models were scanned with Primescan (PR) (Dentsply Sirona). The results for fully edentulous models revealed significantly superior trueness for the scans of the mandibular arch by the inexperienced operator. For the partially edentulous models, the largest deviations were found in the edentulous sites of the anterior maxilla and the free end of the mandible. Regarding the precision, a significantly better result was found for the scans of the edentulous maxillary model by the inexperienced operator. In general, the accuracy results were superior for the partially edentulous models than completely edentulous models. Moreover, statistical analysis revealed a direct correlation between scanning duration and trueness, where the longer scanning duration was associated with superior trueness.[20]

**Palatal area studies**

Out of 4 studies that evaluated the IOS accuracy of the palatal area, 3 were clinical investigations and 1 was a laboratory experiment (Table 6).[18,22,30,31] All of the clinical studies evaluated the accuracy of TR3.[18,30,31] The region of interest in this group of studies was the hard palate in dentate arches of adult participants. Mennito et al. used a fresh cadaver maxilla as the study model and compared the 3D data obtained from 7 different IOSs and the conventional technique against the reference digital data produced by an industrial scanner. Since CO was unable to record the whole maxilla and the palatal area, it was excluded from the analysis. IT Element 2 showed the best trueness for recording the hard palate followed by TR3, IT Element 1, PE, CS3600, and Planscan (PS) (Planmeca). The trueness of the 3D data produced by the stone model was inferior only to the IT Element 2 and TR3. However, none of these differences were statistically significant. Regarding the precision, no significant difference was found between the seven scanners and the conventional technique in recording the palatal mucosa.[22] The effect of palatal width and height on the accuracy of the direct digital scan was assessed in a clinical investigation. The study reported that while there was no correlation between palatal trueness and arch width, deviations of palatal precision increased with increasing arch width. Regarding the palatal vault height, the study found no significant effect on the accuracy of the digital scans.[30] Deferm et al. evaluated the accuracy of IOS through assessments of the scans produced by two operators (experienced and inexperienced). Whereas the difference was not significant, IOS trueness showed fewer deviations for the inexperienced operator. Likewise, the mean absolute error (size measurement) and 90$^{th}$ percentile distance error between the digitized impression and the IOS model were not meaningful.[31] Zhongpeng et al. evaluated the effect of the scanning strategy on the accuracy of the hard palate and palatal vault scans. Their scanning strategies involved increasing the scanning scope or decreasing scanning scope. They reported significant differences in hard palate trueness between the two groups. Higher accuracy was attributed to the decreasing scanning scope when the palatal scan initiated at the palatal side of the posterior teeth in an inverted U-shaped manner toward the posterior teeth on the other side. However, the impact of the different scanning sequences was not notable in the palatal vault.[18]

## Discussion

When scanning an edentulous mucosa is considered, studies showed that the accuracy was influenced by the presence of an artificial marker,[26] distribution and length of the edentulous area,[19,24] operator's experience,[20,31] IOS system characteristics including the head size,[16,20-22,26,28,29,33] soft tissue characteristics (flexibility, mobility, dimension),[23,25,27,29-32] and the scanning strategy.[18,34] Accuracy reports varied among studies according to their different methodologies, evaluated area of interest, and scanning condition. Moreover, the designated reference data was shown to affect accuracy values.[29] The mobile and flexible soft tissues exhibited the highest discrepancies, while the bony structures with attached mucosa showed lower deviations. Nonetheless, the intended clinical application will define the level of required accuracy. The clinically relevant threshold values were varied among the included studies (300 and 500 µm).[18,27,29,33] Yet, in clinical practice, errors of more than 500 µm cannot be considered negligible for the fabrication of a removable denture. In general, most scanners had accuracy values that were acceptable for recording the residual ridge and palate.

The comparison between digital scans of the complete edentulous maxilla and mandible revealed lower accuracy for the mandible when considering both the denture supporting tissues and the peripheral seal zone.[23,29] However, the lower accuracy was associated with the maxilla when the mobile vestibular tissues were excluded from evaluations.[23,27] In addition, the peripheral seal zone was the region with the highest deviations and missed data.[29,32] These findings from the complete arch studies along with results from studies that evaluated the length of edentulism,[16,19,24] can lead to two conclusions. Firstly, the importance of the tissue movement and scanned area on the accuracy of direct digital scans. Secondly, the effect of tissue movement that outweighs the role of the scan area. When considering the whole edentulous arches, lower accuracy was related to the mandible with less denture bearing surface area but more mobile tissues with greater amount of movement (tongue and floor of the mouth). Furthermore, saliva can be controlled more easily in the maxilla. On the other hand, denture congruence with the bearing area is a crucial factor for good retention in a complete denture, or partial dentures with minimum teeth support.[35] Better retention improves the masticatory performance, speaking ability, and patients' quality of life.[36] Therefore achieving maximum denture extension up to the limits of tissue movements should be one of the main goals in removable denture fabrication. However, current IOS technologies are incapable of registering such movements. In general, laboratory studies showed promising results after comparing the IOS and conventional impression/stone model 3D data against the virtualized reference model. [22,28] However, the in vitro outcomes cannot be easily interpreted to confirm the adequacy of IOS as the final impression for all scenarios of removable denture fabrication. Further, the IOS systems can register the soft tissue only in their mucostatic state, which leaves the implementation of relief and pressure to the later stage of the denture design.[37] Potentially, this might lead to more denture post-insertion sore spots and adjustments. In general, it can be assumed that when there are long or multiple spans of partial edentulism, or a fully edentulous arch, the IOS can be safely used as a preliminary impression in the removable denture fabrication process. However, the performance of the IOS as the preliminary impression in a severely resorbed ridge or severe undercuts is not clear as such situations were investigated by the included studies.

Digital solutions in dentistry are developing at a high pace to improve the practicality and quality of prosthetic treatment. For example, the hardware and software updates have been shown to improve data acquisition methods and stitching processes. The accuracy of three generations of Cerec scanners was assessed in the laboratory studies. While Patzelt et al.[21] showed accuracy values of more than 500 µm for CB in simulated edentulous maxillary and mandibular arches, Mennito et al and Kim et al reported the inability of CO in direct digitization of the palatal soft tissue and an edentulous span.[22,26] Only after placement of an artificial marker CO was able to perform a complete scan.[16,22] However, Osnes et al. did not report such a problem with the same device and its updated software and reported a precision of less than 300 µm.[33] Additionally, Schimmel et al. showed the viability of the complete and partial edentulous arch scan with the most recent hardware update (PR). This device indicated less than 500 µm errors in both types of complete and partially edentulous arches.[20]

Concerning the interaction of scanning time and operator's experience, the results were consistent in the studies by Schimmel et al. and Deferm et al.[20,31] In this regard, better accuracy was observed in a longer scanning time for the inexperienced operator. These studies investigated either the simulated models or the relatively dry palatal mucosa. Therefore, this result might not be clinically relevant if the presence of saliva was more significant or if more mobile tissues need to be scanned. Additionally, patient movement can negatively influence the accuracy of the results. Thus, with the current technologies of IOS, short scanning time and operator's experience might be an advantage for more accurate scans. The use of added marker was shown to be effective in reducing the scan time, and improving the reproducibility of the scans.[26] Practical methods for marking the edentulous mucosa in the clinical situation has been suggested in previous reports. Painting pressure indicating paste[10] or composite spheres[38] were offered as a solution for the lack of topology in the edentulous mucosa.

While there is no recommendation from the manufacturers on the scanning strategy for the edentulous mucosa, 2 studies identified a significant effect of the scanning path on the accuracy of the scans.[18,34] The consistent outcomes of these studies showed that decreasing scanning area leads to higher accuracy. This might benefit from reduced stitching error accumulation. Unlike the maxilla, the lower arch form does not lend itself as readily to such a scanning strategy and there is a lack of information regarding an appropriate scanning technique in the mandible. Based on the present review, the literature is still lacking evidence on critical clinical variables such as time efficiency and a standard scanning sequence. Additionally, the majority of the studies were laboratory studies, which may reduce their clinical relevance. More clinical studies are needed to evaluate the clinical impact and long-term outcomes of the dentures fabricated by IOS systems.

## Conclusion

Within the limitations of this systematic review, it appears that the accuracy of IOS can be comparable to the conventional impression if the ridges are firm and covered with attached mucosa. In the context of complete denture fabrication or situations where recording the tissue movement is crucial, the current IOS systems cannot be appropriate alternatives to the conventional techniques unless they were to be used for preliminary impression.

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**Table 1:** Search strategy

| **Search strategy** | **Query** |
|---|---|
| Population #1 | (((("mouth, edentulous"[MeSH Terms] OR ("edentulous"[All Fields]) OR "edentulous mouth"[All Fields]))) OR (partially[All Fields] AND ("jaw, edentulous"[MeSH Terms] OR "edentulous jaw"[All Fields] OR ))) OR ("palate"[MeSH Terms] OR "palate"[All Fields])) OR "edentulous ridge" |
| Intervention #2 | ((((("intraoral scanner") OR "digital impression") OR "optical scanner") OR "3D surface scanning") OR "direct capturing") OR intraoral scan |
| Comparison #3 | (((("dental impression technique"[MeSH Terms] OR ("dental"[All Fields] AND "impression"[All Fields] AND "technique"[All Fields]) OR "dental impression technique"[All Fields])) OR "Conventional impression ") OR "Conventional technique ") OR (("silicon"[MeSH Terms] OR "silicon"[All Fields]) AND impression[All Fields]) |
| Outcome #4 | (((((((("data accuracy"[MeSH Terms]) OR "dimensional measurement accuracy"[MeSH Terms]) OR accuracy) OR precision) OR reliability) OR trueness) OR repeatability)) OR "3D comparison" |

**Table 2:** Quality Assessment of Diagnostic Accuracy Studies (QUADAS) guideline and scoring system

| QUADAS questions | | Score | |
|---|---|---|---|
| | | Yes (1) | No/clear (0) |
| 1 | Was the spectrum of the edentulous mucosa representative of what will be diagnosed in practice? | | |
| 2 | Were selection criteria clearly described? | | |
| 3 | Is the reference method likely to correctly classify the target condition? | | |
| 4 | Is the time period between the reference method and test method short enough to be reasonably sure that the target condition did not change between the two tests? | | |
| 5 | Did the whole sample or a random selection of the sample, received verification using a reference standard of diagnosis? | | |
| 6 | Did the denture related mucosa received the same reference method regardless of the test method results? | | |
| 7 | Was the reference method independent of the test method (i.e. the test method did not form part of the reference standard)? | | |
| 8 | Was the execution of the test method described in sufficient details to permit replication of the test? | | |
| 9 | Was the execution of the reference method described in sufficient details to permit its replication? | | |
| 10 | Were the test results interpreted without knowledge of the results of the reference method? | | |
| 11 | Were the reference method results interpreted without knowledge of the results of the test method? | | |
| 12 | Were uninterpretable/intermediate test results reported? | | |
| 13 | Were withdrawal from the study explained? | | |

**Table 3:** Complete edentulous arch studies

| Author and year | Study quality score (0-13) | Sample size | Scanned surface | Evaluated area (region of interest) | Scanner system | Scanning strategy | Accuracy evaluation method | Reported result |
|---|---|---|---|---|---|---|---|---|
| Patzelt et al, 2013[21] | 11 | 5 per method (one experienced operator) | Edentulous maxilla and mandible study models with soft artificial mucosa | Whole edentulous jaws being cropped proximal to the vestibule | Reference data: Laboratory scanner: Activity 101 (smart optics)<br><br>IOS:<br><br>1. CB (powder required)<br><br>2. LC(powder required)<br><br>3. IT<br><br>4. ZFX | Maxilla: from distobuccal areas, following the crest to the opposite side and then closing the palatal gaps in zig-zag motion over the palate.<br><br>Mandible: from distal area of one side, following the jaw crest to the opposite side in a zig-zag manner. | Superimposition against 3D model obtained from laboratory scanner to measure trueness.<br><br>Superimposition of 3D dataset within each group to measure precision.<br><br>Qualitative evaluation<br><br>Aligning software: Geomagic qualify 2012 by best fit alignment.<br><br>Mean absolute 3D deviations was reported. | Mean trueness (T) and precision (P) values:<br><br>***Maxilla:***<br><br>CB: (T)= 591.8 µm, (P)= 332.4 µm<br><br>IT(3Shape file format): (T)= 144.2 µm (P)= 178.5 µm<br><br>IT (Dental wings file format): (T)= 139.5 µm (P)= 166.8 µm<br><br>LC: (T)= 52.9 µm (P)= 30.8 µm<br><br>ZFX: (T)= 283.8 µm (P)= 425.3 µm<br><br>***Mandible:***<br><br>CB: (T)= 558.4 µm (P)= 698.0 |

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| | | | | | | | | µm<br><br>IT (3Shape file format): (T)= 191.5 µm (P)= 197.9 µm<br><br>IT (Dental wings file format): (T)= 154.7 µm (P)= 217.3 µm<br><br>LC: (T)= 44.1 µm (P)= 21.6 µm<br><br>ZFX: (T)= 253.8 µm (P)= 319.4 µm |
| D'Arienzo et al, 2018[25] | 12 | 1 per method (4 Participants) (one experienced operator) | 1.Edentulous maxilla<br><br>2. stone model obtained from alginate impression in metal impression tray | Whole edentulous jaws being cropped proximal to the vestibule | Reference data: Laboratory scanner: D1000 (3Shape)<br><br>IOS: TR3 | From distobuccal areas of the first quadrant, at the level of the tuber, followed to the crest to the opposite side, passing through the retroincisor papilla, and finally closed the palatal gaps by moving the scanner head in a zig-zag | Superimposition against 3D model obtained from laboratory scanner to measure trueness.<br><br>Qualitative evaluation<br><br>Aligning software: 3DReshaper by best fit alignment.<br><br>The mean 3D differences was reported. | Mean 3D differences for each patient:<br><br>219 µm<br><br>239 µm<br><br>246 µm<br><br>347 µm. |

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| | | | | | | manner. | | |
| Jung et al, 2019[27] | 10 | 1 per method ( 5 Participants) (one experienced operator) | 1.Edentulous maxilla and mandible<br><br>2. stone model obtained from border molded PVS impression (Control) (CI) | Maxilla: Midpalatal raphe, Hard palate, Residual ridge, Soft palate<br><br>Mandible: Residual ridge, Buccal shelf | Reference data: Laboratory scanner: D700 (3Shape)<br><br>IOS: CS3500 | Maxilla: from left to right tuberosity along the posterior palatal seal, next the vestibule and palate were sequentially scanned to overlap with the scanned residual ridge Mandible: from retromolar pad on one side to the contralateral side along the residual ridge followed by buccal vestibular scanning. | Superimposition against 3D model obtained from laboratory scanner to measure trueness.<br><br>Qualitative evaluation<br><br>Aligning software: Geomagic control 2014 by best fit alignment<br><br>Mean 3D difference was reported. | Mean 3D differences :<br><br>***Maxilla:***<br><br>Soft palate: 0.86 mm<br><br>Hard palate: 0.18 mm<br><br>Residual ridge: 0.05 mm<br><br>Midpalatal raphe: 0.05 mm<br><br>***Mandible:***<br><br>Residual ridge: 0.11mm<br><br>Buccal shelf: 0.09 mm<br><br>*Average difference:*<br><br>Mandible: -0.27 mm Maxilla: 0.03 mm |
| Chebib et al, 2019[32] | 9 | 1 per method (12 Participants) (one | 1. Edentulous maxilla<br><br>2. Border | Total impression surface and five region | Reference data: Laboratory scanner: | Not reported (According to the manufactur | Superimposition against 3D model of the control | RMS values<br><br>***Total impression*** |

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| | | experienced operator) | molded ZOE impression (Control)<br><br>3. ALG impression<br><br>4. PVS impression<br><br>5. PVS impression relined with ZOE (PVSM) | of interest:<br><br>Midpalatal raphe<br><br>Peripheral border<br><br>Inner seal<br><br>Residual ridge<br><br>Posterior palatal seal area | Iscan D103i (Imetric)<br><br>IOS: TR3 | er's instruction) | group obtained from laboratory scanner to measure trueness.<br><br>Qualitative evaluation<br><br>Aligning software: Geomagic control X by best fit alignment<br><br>Root mean square value was reported | ***surface:***<br><br>ALG: 1.23 mm<br><br>PVS: 0.75 mm,<br><br>PVSM: 0.75 mm<br><br>TRI: 0.70 mm |
| Braian et al, 2019[16] | 9 | 15 per method (one experienced operator) | CAD-CAM metal alloy (Remanium-Star-CL) model with five markers (***Description:*** airborne-particle abrasion for a non-reflective surface of a fully edentulous mandibular ridge (E) and a fully dentate mandibul | Distance between five cylinders:<br><br>Cross arch:<br><br>P1-P2, P1-P3, P1-P4, P1-P5<br><br>Intercylindrical:<br><br>P1-P2, P2-P3, P3-P4, P4-P5 | Reference data: Coordinates measuring machine<br><br>IOS:<br><br>1.CO<br><br>2.IT Element 1<br><br>3.PE<br><br>4.CS3600<br><br>5.TR3 | From left distal site continued to distal right (According to the manufacturer's instruction for each scanner) | Measurement of the distance between markers in the dentate arch and the edentulous arch and comparison with the reference data as the true value. | For the intercylindrical data on the edentulous cast, the IOS devices presented trueness values ≤94 mm (except, CS 3600, P1-P2, −103 µm) and precision values ≤97 µm.<br><br>The trueness values for the cross-arch measureme |

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| | | | ar arch (D)) | | | | | nts on the edentulous cast were ≤193 µm and the precision values, ≤299 µm (except PE edentulous arch, P1-P5, 441 µm). |
| Osnes et al, 2020[33] | 10 | 5 per method (One experienced operator) | Metal edentulous maxillary model | Whole edentulous jaws cropped to retain the functional depth and width of the sulcus and to the post dam region. | IOS:<br>1.TD (powder required)<br>2.PE<br>3.CO<br>4. DW<br>5. TR3<br>6.AD | Not reported. | Superimposition of 3D datasets within each group to measure precision.<br>Qualitative evaluation<br>Aligning software: custom alignment software by generalized iterative closest point algorithm.<br>Signed mean deviations and unsigned medians of the poorest 1% of the surface were reported. | ***The mean distance of the medians of the poorest fitting 1% :***<br>TD: 0.103 mm, PE: 0.53 mm, CO: 0.153 mm, DW: 0.452 mm, TR3: 0.092 mm, AD: 0.040 mm<br>***Signed mean deviations***<br>TD: 0.025 mm<br>PE: 0.087mm<br>CO: 0.032 mm<br>DW: 0.097 mm<br>TR3: 0.026 mm<br>AD: 0.003 |

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| Lo Russo et al, 2020[23] | 9 | 1 per method (10 Participants) (one experienced operator) | 1.Edentulous maxilla and mandible (Control)<br><br>2. Polysulfide impression | 1. Whole edentulous jaws<br><br>2. Whole edentulous jaws excluding peripheral borders | Reference data: TR3<br><br>IOS: TR3 | Not reported | Superimposition against 3D model obtained from IOS to measure trueness.<br><br>Qualitative evaluation<br><br>Aligning software: Geomagic wrap 2017 by best fit alignment.<br><br>Mean 3D distance between two digital models was reported. | Mean distance<br><br>***Full scans:***<br><br>Maxilla: -0.11 mm<br><br>Mandible: -0.26 mm<br><br>***Trimmed scans:***<br><br>Maxilla: -0.03 mm<br><br>Mandible: -0.02 mm |
| Hack et al, 2020[29] | 12 | 3 per method (29 Participants- 27 maxilla- 5 mandible) | 1.Edentulous Maxilla and mandible<br><br>2. border molded PVS impression<br><br>3. Stone model obtained from the impression | Whole edentulous jaws (bearing area and periphery) | Reference data: Laboratory scanner: D700 (3Shape)<br><br>IOS: LC **or** TD | Maxilla: from the region of the right tuberosity continued with a zig-zag-manner in anterior region. Then, the scan was saved, and a scan of the anterior vestibule was taken. The scans were automatica | Superimposition of 3D model against each other to measure trueness.<br><br>Qualitative evaluation<br><br>Aligning software: Geomagic qualify 2013 by best fit alignment.<br><br>Mean 3D difference were | The overall mean difference<br><br>Stone model to IOS: 336.7 µm (n= 32)<br><br>Conventional impression to IOS: 363.7 µm (n= 24)<br><br>Conventional impression to stone model: 272.1 µm |

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| | | | | | | lly aligned, fused, and saved.<br><br>Mandible: from the right retromolar pad area followed the anatomy of the lower jaw in a zig-zag-manner to the opposing site. The scans were saved, an additional scans of the vestibule and sublingual areas were added. | reported | (n= 29) |
| Zarone et al, 2020[34] | 12 | 10 per method (One experienced operator) | Edentulous maxillary models (polyurethane resin) (***Description:*** presence of palatal rugae (wrinkle model), absence of palatal rugae (smooth model)) | Whole edentulous jaws (bearing area and periphery) | Reference data: metrological scanning machine (Atos Core 80; GOM)<br><br>IOS: TR3 | Buccopalatal technique (BP): started from left tuberosity across the ridge and then towards buccal vestibule continued to palatal from the posterior to anterior.<br><br>S-shaped technique (SS): | Superimposition against 3D model obtained from laboratory scanner to measure trueness.<br><br>Superimposition of 3D dataset within each group to measure precision.<br><br>Qualitative evaluation<br><br>Aligning | Trueness:<br><br>WT/BP: 48.7 µm<br><br>WT/SS: 65.9 µm<br><br>WT/PB: 109.7 µm<br><br>ST/BP: 48.1 µm<br><br>ST/SS: 56.4 µm<br><br>ST/PB: 61.1 µm<br><br>Precision:<br><br>WT/BP: |

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| | | | | | | started in an S-shape pattern across the ridge and its buccal and palatal slobs and then toward remaining palatal area from posterior to anterior<br><br>Palatobuccal technique (PB): started from left tuberosity across the ridge and then towards palatal region in an inverted U-shape, finished in buccal vestibule at the side of starting point | software: Geomagic Control X by best fit alignment<br><br>Mean 3D differences were reported | 46.7 µm<br><br>WT/SS: 53.9 µm<br><br>WT/PB: 90 µm<br><br>ST/BP: 46 µm<br><br>ST/SS: 76 µm<br><br>ST/PB: 52.9 µm |

**Table 4:** Partially edentulous arch studies

| Author and year | Study quality score (0-13) | Sample size | Scanned surface | Evaluated area (region of interest) | Scanner system | Scanning strategy | Accuracy evaluation method | Reported result |
|---|---|---|---|---|---|---|---|---|
| Kim et al, 2017[26] | 10 | 5 per method (one operator) | Dental model with hard artificial mucosa (***Description:*** Partially edentulous mandible: (Cl III MOD 1- missing right second premolar, first molar and left premolars and first molar) | Only 26 mm of edentulous space on the left quadrant, with presence and absence of an artificial marker. | Reference data: Laboratory scanner: Identica Hybrid, (Medit)<br><br>IOS: 1. CS3500,<br><br>2. CO<br><br>3. TR3 | Not reported<br><br>(According to the manufacturer's instruction) | Superimposition against 3D model obtained from reference scanner to measure trueness.<br><br>Superimposition of 3D dataset within each group to measure precision.<br><br>Aligning software: Rapidform 2006 by three-point registration and fine registration<br><br>Mean discrepancy value was reported. | Trueness:<br><br>TR3: No marker: 36.1 Marker: 30.6<br><br>CS3500: No marker: 38.8 Marker: 26.7<br><br>CO: No marker: Not obtained, Marker: 31.8<br><br>Precision:<br><br>TR3: No marker: 13.0 Marker: 9.2<br><br>CS3500: No marker: 43.6 Marker: 12.4<br><br>CO: No marker: Not obtained, Marker: |

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| | | | | | | | | 10.5 |
| Hayama et al, 2018[28] | 9 | 5 per method (one experienced operator) | 1. Dental model with silicon artificial mucosa (***Description:*** Partially edentulous mandible: (Cl I- bilateral missing second premolar and molars/ Cl III- left second premolar and first molar))<br>2. Stone model obtained from PVS impression with selective pressure technique. | 1. Whole model<br>2. Mucosal area only | Reference data and stone models: Laboratory scanner: ARCTICA Auto Scan, (KaVo)<br>IOS: CS3500 Large head (16×12) and small head (12×9) | From left central proceeded to distal area and ended at the right central incisor by moving to the right dental arch. | Superimposition of digitized stone model and digital data against 3D ref model obtained from laboratory scanner to measure trueness.<br>Superimposition of 3D dataset within each group to measure precision.<br>Qualitative evaluation<br>Aligning software: Geomagic Studio 2014 by best fit alignment.<br>Median of the root mean square (RMS) value was reported. | ***Whole model:*** **Trueness:**<br>large head: 105-108 µm,<br>small head: 115-158 µm<br>conventional method:122-157 µm<br>**Precision:**<br>large head: 100-114 µm,<br>small head: 179-192 µm<br>conventional method:77-119 µm<br>***Mucosal area:*** **Trueness:**<br>large head: 54-107 µm,<br>small head: 76-180 µm<br>conventional method:122-152 µm |

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| | | | | | | | | **Precision:**<br>large head: 109-121 µm,<br>small head: 169-215 µm<br>conventional method:52-90 µm |
| Lee et al, 2019[24] | 11 | 6 per method per model (one experienced operator) | Dental model with hard artificial mucosa (***Description:*** Fully dentate maxilla (control), Partially edentulous maxilla: (1. Cl III-missing right second premolar and first molar/ 2. Cl III MOD 1-missing right second premolar, first molar and left premolars and first molar/ 3. CL IV-missing incisors and right canine/ 4. Cl III | Complete arch excluding palatal area | IOS:<br>1. CS3600<br>2. i500 | From second molar with the smaller edentulous side between the second molars following the manufacturers' guideline. | Superimposition of 3D datasets within each group to measure precision.<br>Qualitative evaluation<br>Aligning software: Geomagic Control X by best fit alignment.<br>Root mean square (RMS) value was reported. | CS3600<br>Control: 44.37 µm<br>Case1: 49.57 µm<br>Case2: 96.31 µm<br>Case3: 85.59 µm<br>Case4: 103.28 µm<br>i500<br>Control: 52.30 µm<br>Case1: 58.43 µm<br>Case2: 100.22 µm<br>Case3: 106.71 µm<br>Case4: 115.66 µm |

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| | | | MOD 1- missing left second premolar, first molar and four incisors)) | | | | | |

**Table 5:** completely and partially edentulous arch studies

| Author and year | Study quality score (0-13) | Sample size | Scanned surface | Evaluated area (region of interest) | Scanner system | Scanning strategy | Accuracy evaluation method | Reported result |
|---|---|---|---|---|---|---|---|---|
| Tasaka et al, 2019[19] | 8 | 5 per model and per operator (5 experienced operators) | 1. Dental model with silicon artificial mucosa mounted in a manikin with a face mask. (***Description:*** Fully edentulous maxilla<br><br>Partially edentulous mandible ( Cl I- missing bilateral molars and left second premolar)) | Three regions in maxilla: premolar, molar in coronal section, and midline in sagittal section<br><br>Two regions in mandible: crest of the ridge on both sides in sagittal section | Reference data: Laboratory scanner: D900 (3Shape)<br><br>IOS: TR2 | Zig-zag manner | Superimposition against 3D model obtained from laboratory scanner to measure trueness.<br><br>Aligning software: 3Shape CAD software by three points.<br><br>Vertical maximum distance of the difference and the integral value were reported. | The means of five operator:<br><br>Maximum distance of the difference: Maxilla (premolar: 0.3 mm, molar: 0.18 mm, midline: 0.18 mm) Mandible: (right side: 0.05 mm, left side: 0.08 mm) |

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| | | | | | | | | The integral value : Maxilla: ( premolar : 4.17 $mm^2$, molar:6.82 $mm^2$, midline: 4.70 $mm^2$) Mandible: (right side: 0.78 $mm^2$, left side: 1.60 $mm^2$) |
| Schimmel et al, 2020[20] | 10 | 10 per model and per operator (one experienced and one inexperienced operator) | 1. Dental model with silicon artificial mucosa mounted in a manikin with a face mask. (***Description:*** Fully edentulous maxilla and mandible<br><br>Partially edentulous maxilla (Cl III MOD 2- missing bilateral first premolar and molar and four incisors) and mandible | Extension of the future complete or partial removable prosthesis 2mm short of the mucobuccal fold. | Reference data: Industrial scanner: ATOS Capsule 200MV120, (GOM)<br><br>IOS: PR | Not reported. | Superimposition against 3D model obtained from reference scanner to measure trueness.<br><br>Superimposition of 3D dataset within each group to measure precision.<br><br>Qualitative evaluation<br><br>Aligning software: GOM Inspect Professional by best fit alignment.<br><br>Median of the absolute deviation was | Overall median trueness: 24.2 µm<br><br>Overall median precision : 18.3 µm |

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| | | | (Cl II MOD 2-missing right molars, left first molar, and four incisors)) | | | | | reported. | |

**Table 6:** Palatal area studies

| Author and year | Study quality score (0-13) | Sample size | Scanned surface | Evaluated area (region of interest) | Scanner system | Scanning strategy | Accuracy evaluation method | Reported result |
|---|---|---|---|---|---|---|---|---|
| Gan et al, 2016[30] | 11 | 3 per participant (32 participant) (one experienced operator) and 1 reference model per participant | 1.Whole maxillary arch (natural dentition and palate)<br><br>2. Stone models obtained from two-step putty-wash impression. | 1.Complete dental arch<br><br>2.Palatal soft tissue only(palatal soft tissue beyond the second molars were excluded) | Reference data: Laboratory scanner: D500 (3Shape)<br><br>IOS: TR3 | Palatal soft tissue: From palatal side of the central to the distal end of the second molar in a zig-zag manner. | Superimposition against 3D model obtained from laboratory scanner to measure trueness.<br><br>Superimposition of 3D dataset within each group to measure precision.<br><br>Qualitative evaluation<br><br>Aligning software: Geomagic Studio 12 by the best fit alignment.<br><br>The mean | ***Palatal soft issue:***<br><br>Trueness: 130.54 µm (positive deviations: 185.84 µm and negative deviations: 75.23 µm)<br><br>Precision: 55.26 µm<br><br>***Full dentition:***<br><br>Trueness:80.01 µm (positive deviations: 96.24 µm and negative deviations: 63.78 µm)<br><br>Precision: |

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| | | | | | | | deviation was analyzed. | 59.52 µm |
| Deferm et al, 2018[31] | 11 | 1 per operator (one experienced and one inexperienced operator) and 1 reference impression per participant (10 participant) | 1.Whole maxillary arch (natural dentition and palate)<br>2. irreversible hydrocolloid impression | Hard palate (palatal soft tissue beyond the second molars were excluded) | Reference data: Laboratory scanner: D500 (3shape)<br>IOS: TR3 | Not reported | Superimposition against 3D model obtained from laboratory scanner to measure trueness.<br>Superimposition of 3D dataset within each group to measure precision.<br>Aligning software: Maxilim by the iterative closest point algorithm.<br>The absolute average distance and absolute 90th percentile distance was reported. | **Trueness:**<br>*Mean absolute distance*<br>Inexperienced Operator: 0.12 mm<br>Experienced operator: 0.14 mm<br>*Absolute 90th percentile distance*<br>Inexperienced Operator: 0.23 mm<br>Experienced operator: 0.28 mm<br>**Precision:**<br>*Mean absolute distance:* 0.08<br>*Absolute 90th percentile distance:* 0.16 |
| Mennito et al, 2019[22] | 8 | 5 per method (experienced operators with each scanner) | 1.Whole Fresh cadaver maxilla (natural dentition with three | 1. Complete dental arch<br>2. Crown preparati | Reference data: Industrial scanner: ATOS Capsule | Not reported | Superimposition of digitized stone model and digital data against 3D ref | ***Palatal soft tissue:***<br>Trueness:<br>Physical :122 µm /TR3: 134 |

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| | | | prepared teeth and palate)<br><br>2. stone models obtained from two-stage PVS impression | on only<br><br>3. Palatal soft tissue only | (GOM)<br><br>Stone model: laboratory scanner: D800 (3Shape)<br><br>IOS:<br><br>1. TR3<br><br>2. CO<br><br>3. CS3600<br><br>4. IT Element 1<br><br>5. IT Element 2<br><br>6. PE<br><br>7. PS | | model obtained from reference scanner to measure trueness.<br><br>Superimposition of 3D dataset within each group to measure precision.<br><br>Qualitative evaluation<br><br>Aligning software: Geomagic Control X by best fit alignment. | µm CO: not reported /CS3600:228 µm / IT Element 2: 106 µm/ IT Element 1:139 µm/ PE: 150 µm/ PS: 236 µm<br><br>Precision:<br><br>Physical: 64 µm/ TR3: 109 µm/ CO: not reported/ CS3600:117 µm/ IT Element 2: 68 µm/ IT Element 1: 79 µm/ PE: 87 µm/ PS: 71 µm |
| Zhongpeng et al, 2019[18] | 12 | 1 per method (35 Participants) (one experienced operator) | 1.Whole maxillary arch (natural dentition and palate)<br><br>2. Stone models obtained from one-step PVS impression. | 1. Dentition.<br><br>2. Palatal soft tissue.<br><br>-Hard palate<br><br>-Palatal vault | Ref data: Laboratory scanner: R700 (3Shape)<br><br>IOS: TR3 | T1: from the palatal side of upper central incisors to the distal end of the second molar in a zigzag manner.<br><br>T2: from palatal side of the upper second molar to palatal side of | Superimposition against 3D model obtained from laboratory scanner to measure trueness.<br><br>Intraclass correlation coefficient was calculated to verify reproducibility of the superimposition (Palatal-level | **Trueness**<br><br>T1:<br><br>hard palate: 118.59 µm<br><br>Palatal vault: 127.35 µm<br><br>T2:<br><br>Hard palate: 108.25 µm<br><br>Palatal vault: 118.17 µm |

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| | | | | | | the opposite arch, finishing the entire palatal scanning at the distal end of the second molars by continuously narrowing down the scope in an inverted U manner | method) in each region.<br>Qualitative evaluation<br>Aligning software: Rapidform by best fit algorithm<br>Mean absolute deviation was reported. | |

Figure 1: Flowchart of the literature search according to PRISMA guidelines