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Systematic Review

Accuracy, reliability, and efficiency of intraoral scanners for full-arch impressions: a systematic review of the clinical evidence

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Summary

Objectives: The interest on intraoral scanners for digital impressions has been growing and new devices are continuously introduced on the market. It is timely to verify whether the several scanners proposed for full-arch digital impressions have been tested under clinical conditions for validity, repeatability, reproducibility, as well as for time efficiency, and patient acceptance.
Search methods: An electronic search of the literature was conducted through PubMed, Scopus, Cochrane Library, Web of Science, and Embase, entering the query terms 'digital impression', 'intraoral digital impression', 'intraoral scanning', 'intraoral scanner', 'intraoral digital scanner', combined by the Boolean operator 'OR'. No language or time limitation was applied.
Selection criteria: Only studies where digital full-arch impressions had been recorded intraorally were considered.
Results: In only eight studies full-arch scans had been performed intraorally. Only four studies reported data on validity, repeatability, reproducibility of digital measurements and their samples were limited to subjects in complete permanent dentition. Only two intraoral scanners, Lava COS and iTero, were tested. Scanning times were measured in six studies and varied largely. Patients' acceptance of intraoral scanning was evaluated in four studies, but it was not specifically assessed for children.
Conclusions: The scientific evidence so far collected on intraoral scanning is neither exhaustive, nor up-to-date. Data from full-arch scans performed in children should be collected. For a meaningful assessment of time efficiency, agreement should be reached on the procedural steps to be included in the computation of scanning time.

Introduction

One of the latest innovations in digital orthodontics has been the introduction of intraoral scanners, chairside devices that scan the patient's dentition as an alternative to the use of conventional impression materials (1–5). The development of digital models has several advantages that include reduced storage requirement, rapid access to 3D diagnostic information, and easy transfer of digital data for communication with professionals and patients (5–8). Additionally, digital dental models allow to create virtual set-ups for enhanced treatment planning and fabrication of custom made removable and fixed appliances (5, 6, 8). The interest on intraoral scanners has been growing and new devices are continuously launched. In a recent overview on intraoral digital scanners Kravitz *et al.* (8) stated that the replacement of alginate impressions with these new devices represents a paradigm shift in orthodontics. However, in order to support such a statement, evidence should be provided that accuracy, reliability, time requirement, and patient perception of the several available intraoral scanners are comparable to that of the

conventional technique for full-arch impressions (9). Particularly, the evidence should include data from full-arch digital impressions recorded intraorally. Therefore, the present review aimed at systematically assessing the existing literature, in order to verify whether current scanning systems for complete-arch digital impressions have been tested under clinical conditions for validity, repeatability, reproducibility of digital measurements, as well as for time efficiency and patient acceptance. Validity, repeatability, and reproducibility appraise the accuracy and reliability of a measurement. Validity is defined as the extent to which a measurement measures what it purports (10), and has commonly been assessed as the closeness of software measurements on digital models with caliper measurements on stone models (1, 9, 11). The term 'accuracy' has also been used to describe such parameter (1). Repeatability refers to the consistency between replicated measurements (10), while reproducibility is determined by the inter-examiner agreement (1). In keeping with PRISMA guidelines for systematic reviews (12), the research question was formulated with reference to the intervention (full-arch digital impressions), outcome (validity, repeatability, reproducibility, time efficiency, patient acceptance), and study design (*in vivo* study) parameters of the PICOS method (12), while no limitation was given as to the type of patient participating in the study. The protocol was not registered before starting the systematic review.

Materials and methods

Search

An electronic search of the literature was conducted through the following databases: PubMed, Scopus, Cochrane Library, Web of Science, Embase. The survey covered the period from inceptions to the last access on 30 June 2015 with no language restrictions. The following query terms were used: digital impression, intraoral digital impression, intraoral scanning, intraoral scanner, intraoral digital scanner. The query terms were combined by the Boolean operator 'OR' in order to prompt a broad-based survey of the available literature. The search strategy followed to investigate each database is shown in Table 1.

Eligibility criteria

In order to be included in the review, the paper had to meet the following criteria: 1. To be a study on full-arch digital impressions recorded intraorally; 2. To be a study assessing any of the following outcomes: validity, repeatability, reproducibility, time efficiency, patient acceptance of digital impressions. Conversely, the exclusion criteria were stated as follows: 1. Dual publications; 2. Studies *in vitro* or *ex vivo;* The retrieved items were screened based on a three-stage selection process, that subsequently considered titles, abstracts, and full texts. At stage 1 a list of titles was obtained from the database and titles that clearly did not refer to intraoral full-arch impressions were excluded. At stage 2 the abstracts of the selected titles were screened and, if it was clear from the abstract text that the paper did not deal with intraoral full-arch impressions, it was excluded from the review. At stage 3 full-text articles were carefully read and it was verified whether the studies were relevant to the objectives of the review.

Data items

The following data were extracted: sample size, inclusion/exclusion criteria, methods of intraoral scanning, recorded measurements, assessment of validity, repeatability, and reproducibility of digital measurements, measured scanning time, patient's acceptance of intraoral scans.

Additional analyses

Papers referenced in the selected studies were added to the reviewed literature if pertinent. Additionally, the Google search engine was used to identify on Internet the web pages of current manufacturers of intraoral scanners. The web was browsed by entering in the Google search box the same query terms as those used in the database search. Up to 10 pages of the Google search were screened (13). Then, the attention was focused on the web sites of intraoral scanners for use in Orthodontics.

Assessment of risk of bias

The studies reporting data on validity, repeatability, reproducibility of digital measurements were evaluated with reference to the Quality Assessment of Diagnostic Accuracy Studies (QUADAS) checklist (14, 15).

Two investigators (CG and LF) independently selected the papers and rated their quality. The interexaminer agreement on QUADAS-2 judgements (15) was measured with the Cohen's Kappa Coefficient. A 0.929 coefficient was calculated, indicative of a very high agreement. Nevertheless, in case of conflicting decision the two examiners discussed until consensus was reached.

Results

Study selection

Figure 1 presents a flow chart of article selection. From the items retrieved by the keyword-based search of databases duplicates and any study not dealing with full-arch scans were eliminated. Sixteen papers were thereby identified as relevant. The selected articles were

Table 1. Search strategy for each database and relative results

Database	Search strategy	Results
PubMed	(digital impression) OR (intraoral digital impression) OR (intraoral scanning) OR (intraoral scanner) OR (intraoral digital scanner)	725
Scopus	'digital impression' OR 'intraoral digital impression' OR 'intraoral scanning' OR 'intraoral scanner' OR 'intraoral digital scanner'	196
Cochrane Library	'digital impression' OR 'intraoral digital impression' OR 'intraoral scanning' OR 'intraoral scanner' OR 'intraoral digital scanner'	3
Web of Science	'digital impression' OR 'intraoral digital impression' OR 'intraoral scanning' OR 'intraoral scanner' OR 'intraoral digital scanner'	1529
Embase	digital AND impression OR intraoral AND digital AND impression OR intraoral AND scanning OR intraoral AND scanner OR intraoral AND digital AND scanner	47

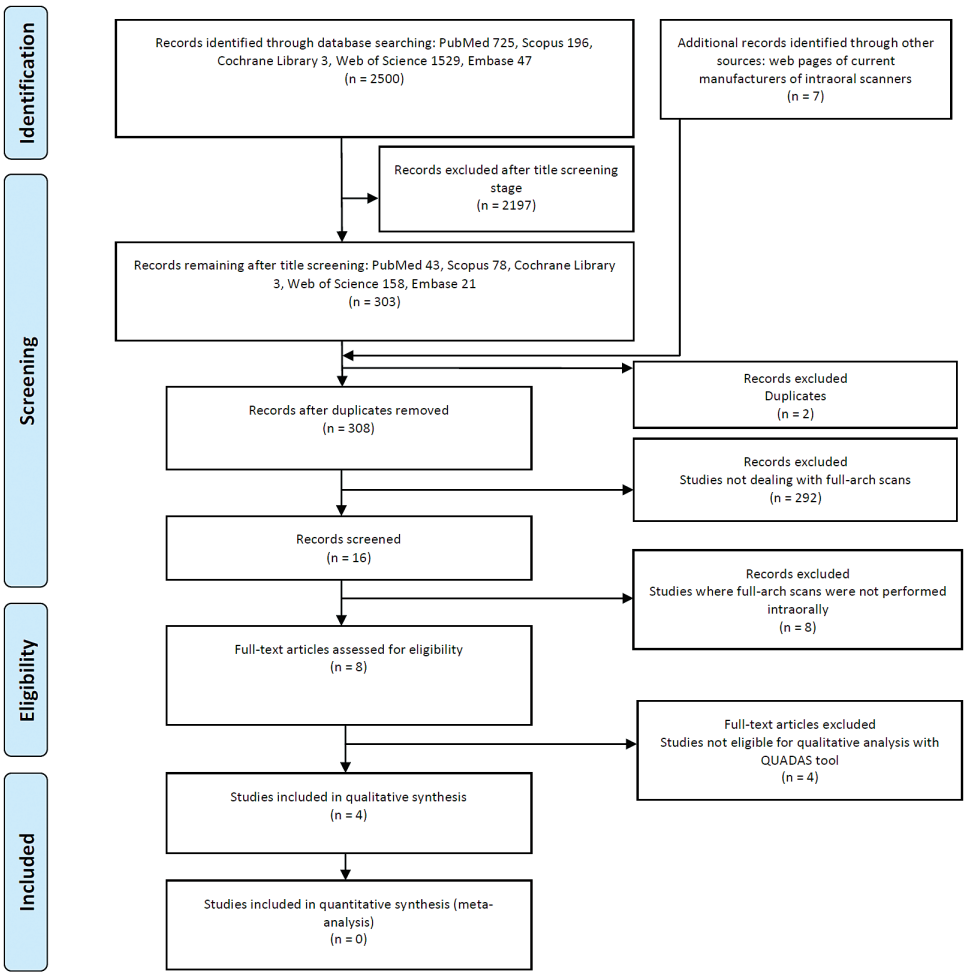

Figure 1.

all in English language. In only eight of these studies full-arch scans had been performed intraorally (1, 9, 11, 16–20), rather than on dry skulls, reference models or conventional impressions. Scanning time was assessed in six studies (11, 16–20), while patients' perception was addressed in four papers (17–20). Only four studies reported data on validity, repeatability, reproducibility of digital measurements (Table 2) (1, 9, 11, 20). Among the latter studies, in the investigation by Naidu and Freer (1) (Table 2), following a power analysis, a sample of 30 subjects was collected to assess validity, reliability, and reproducibility of tooth widths measurements on digital models obtained with the iOC/OrthoCAD system. For validity assessment, caliper measurements on stone models were taken as the true values. Although a statistically significant difference in tooth widths emerged between caliper and digital method, such discrepancy was considered of questionable practical significance (1). Reliability and reproducibility were rated as excellent (1). In the study by Wiranto *et al.* (11) (Table 2), 22 volunteers received alginate impressions that were then poured with plaster. Caliper measurements on stone models were compared with software measurements (Digimodel) on Lava intraoral scans and on digitized models (11). It was concluded that both scanning systems were valid, reliable, and reproducible methods to obtain linear tooth measurements (11). Flügge *et al.* (9) compared in one participant intraoral scans and model scans acquired with iTero, as well as model scans digitized with the bench scanner D250 (Table 2). Intraoral scanning with iTero was found to be less accurate than extraoral scanning with the same device, pointing out that intraoral conditions challenged the quality of scanning (9). Additionally, models digitized with iTero were less accurate than those obtained with the bench scanner (9). Grünheid *et al.* (20) tested Lava COS on 15 consecutive patients with complete permanent dentition presenting for routine orthodontic treatment at an academic institution (Table 2). Intraoral scans and alginate impressions scans were found to be comparably accurate (20).

When assessing the quality of the four selected studies with reference to the QUADAS tool (Table 2) (14, 15), it emerged that none of them was adequate with regard to sample selection. Particularly, the spectrum of patients could not be considered as representative of the patients who would receive the test in practice, as it included only subjects in complete permanent dentition from first molar to first molar, therefore excluding children. Moreover, in the study by Wiranto *et al.* (11), subjects with severely crowded dentition (crowding > 6mm) were excluded, while in the investigation by Flügge *et al.* (9) only one subject with a Class I occlusion was enrolled. Additionally, in the study by Flügge *et al.* (9), as well as in the paper by Grünheid *et al.* (20), caliper measurements on stone models were not provided as reference standards of accuracy (14). With regard to the parameter 'adequate description of the index test' (14), three studies (9, 11, 20) provided a detailed explanation of the intraoral scanning procedure.

Table 2. Characteristics and QUADAS-2 (14, 15) judgements of the studies included in the qualitative analysis

Paper	Naidu and Freer (1)	Flügge *et al.* (9)	Wiranto *et al.* (11)	Grünheid *et al.* (20)
Sample	30 subjects at the School of Dentistry at the University of Queensland	1 subject	22 volunteers, employees of the Department of Orthodontics and students of the Department of Dentistry of the University of Groningen	15 consecutive patients from the Division of Orthodontics at the School of Dentistry of the University of Minnesota
Inclusion/Exclusion criteria	Full complement of permanent teeth from first molar to contralateral first molar; No missing or heavily restored teeth; No teeth with large carious lesions or enamel defects that would affect the mesiodistal morphology of the crown	Class I occlusion; Full dentition	Complete permanent dentition from first molar to first molar; no fixed orthodontic appliances; no severe crowding (<6 mm)	Full permanent dentition from first molar to first molar; no remaining deciduous teeth; no impacted teeth; no supernumerary teeth
Compared methods	Alginate impressions poured in stone; Intraoral scanning with iOC scanner (Cadent)	Intraoral scanning with iTero (Align Technologies); Model scanning with iTero; Extraoral Model scanning with D250 scanner (3Shape)	Alginate impressions poured in stone; Alginate impressions digitized with computed tomography scanner OrthoProof; Intraoral scanning with Lava COS (3M ESPE)	Alginate impressions digitized with computed tomography scanner (OrthoProof); Intraoral scanning with Lava COS (3M ESPE); Model scanning with Lava COS; Model scanning with R700 scanner (3 Shape)
Recorded measurements	Tooth width; anterior Bolton ratio; overall Bolton ratio	Deviations between corresponding models	Tooth width; anterior Bolton ratio; overall Bolton ratio	Differences in tooth positions between digitally superimposed models
Assessed parameters	Validity; reliability; reproducibility	Precision (reliability)	Validity; reproducibility	Accuracy
Statistical tests	Validity: 2-tailed paired *t*-test; reliability: Pearson correlation coefficient; reproducibility: Bland–Altman analysis	Kolmogorov–Smirnov test	Intraclass correlation coefficients; paired *t*-test	Bland–Altman method
Conclusions	The iOC/OrthoCAD system can be used to measure tooth widths and calculate Bolton ratios with clinically acceptable accuracy and excellent reliability and reproducibility.	Scanning with the iTero is less accurate than scanning with the D250. Intraoral scanning with the iTero is less accurate than model scanning with the iTero	Both intraoral scanning and CBCT scanning of alginate impressions are valid, reliable, and reproducible methods to obtain dental measurements for diagnostic purposes.	Digital models produced from intraoral scans can be as accurate as those from alginate impressions.

Paper	QUADAS-2 judgements						
	Risk of bias				Applicability concerns		
	Patient selection	Index test	Reference standard	Flow and timing	Patient selection	Index test	Reference standard
Naidu and Freer (1)	–	–	+	+	–	–	+
Flügge *et al.* (9)	–	+	–	+	–	+	–
Wiranto *et al.* (11)	–	+	+	+	–	+	+
Grünheid *et al.* (20)	–	–	+	+	–	–	+

+, low risk of bias; –, high risk of bias.

The time requested for digital acquisition of the full dentition was measured in six studies (11, 16–20) (Table 3). Lava COS scanner was tested in three investigations (11, 18, 20). Wiranto *et al.* (11) reported that the scanning times following cotton rolls placement and teeth powdering ranged from 14 to 40 minutes, with an average of 23 minutes. Conversely, Grünheid *et al.* (20) included also moisture control, powdering, and removal of isolation materials in the calculation of the chairside time for Lava COS scans that was on average 20 minutes and 27 seconds, with a standard deviation of 3 minutes and 6 seconds. In the study by Vasudavan *et al.* (18), orthodontic assistants required between 16 and 46 minutes (mean 26 minutes) for complete intraoral scanning. No information about the time interval considered as 'scanning time' was provided (18). A trend toward the decrease in scanning times as the operator gained experience was observed in all the studies testing Lava COS (11, 18, 20). The studies by Garino *et al.* (16, 17) involved the powder-free

Table 3. Summary of the findings of studies assessing scanning time

Paper	Scanner	Sample size	Measured scanning time	Procedures preceding or following intraoral scans included in the computation of scanning time
Wiranto *et al.* (11)	Lava COS (3M)	22	Range: 14–40 min	Cotton rolls placement and powdering
Garino *et al.* (16)	iTero (Align Technology)	328	Mean: 11 min 58 s; range: 6–8 min	—
Garino and Garino (17)	OrthoCAD iOC (Cadent)	120	Mean: 16.7 min for the first 40 patients, 9.5 min for the last 20 patients	Bite registration
Vasudavan *et al.* (18)	Lava COS (3M)	30	Mean: 26 min; range: 16–46 min	No information provided
Yuzbasioglu *et al.* (19)	CEREC Omnicam (Sirona)	24	Mean: 248.48 s	Patient information, laboratory prescription, bite scan
Grünheid *et al.* (20)	Lava COS (3M)	15	Mean: 20 min 27 s	Moisture control, powdering, removal of isolation material

Table 4. Summary of the findings of studies assessing patient's acceptance of intraoral scans

Paper	Scanner	Sample size	Patients' preference for intraoral scanning over conventional impressions (%)	Impression material
Garino *et al.* (17)	OrthoCAD iOC (Cadent)	120	100	Not specified
Vasudavan *et al.* (18)	Lava COS	30	77	Alginate
Yuzbasioglu *et al.* (19)	CEREC Omnicam (Sirona)	24	100	Polyether
Grünheid *et al.* (20)	Lava COS (3M)	15	27	Alginate

scanner iTero. From 328 scans an average of 11 minutes and 58 seconds was calculated, although the scanning times varied between 6 and 18 minutes (16). Also, when using iTero, the existence of a learning curve was documented: in a sample of 120 patients, the average scanning time, bite registration included, decreased from 16.7 minutes of the first 40 patients to 9.5 minutes of the last 20 cases (17). Yuzbasioglu *et al.* (19) tested CEREC Omnicam in a sample of 24 adults and found that the mean scanning time (248.48 ± 23.22 seconds) was significantly shorter than the time needed for conventional impression taking with a polyether material (605.38 ± 23.66 seconds).

Patients' acceptance of the new technology of intraoral scanning was evaluated in four studies (17–20) (Table 4). One hundred percent of the 120 patients surveyed by Garino *et al.* (16) reported to prefer iTero scanning over conventional impressions. It was not indicated what impression material was used (18). In the investigation by Yuzbasioglu *et al.* (19), all the patients, who were at their first experience with dental impressions, preferred to receive intraoral scans with the Cerec OMNICAM device rather than polyether impressions. Digital scanning with Lava C.O.S. was preferred over conventional alginate impressions by 77% of the patients surveyed by Vasudavan *et al.* (18). Conversely, in the study by Grünheid *et al.* (20) the large majority of patients (73%) preferred alginate impressions to Lava COS intraoral scans.

Discussion

It was a remarkable observation that only few studies have evaluated complete-arch scans acquired directly in the patient's mouth (1, 9, 11, 16–20). Although verification of accuracy and reliability should be a prerequisite for the clinical application of any new technology, only four studies on intraoral scanners have pursued this objective under intraoral conditions (1, 9, 11, 20). Moreover, although several intraoral scanners have been commercialized for use in orthodontics (4, 5, 8, 21–27), only two of them, Lava COS and iTero, have been tested in the clinical setting. Therefore, the scientific evidence so far collected on intraoral scanning is neither exhaustive, nor updated. It should also be pointed out that accuracy and reliability were comprehensively evaluated in only one paper (1). Wiranto *et al.* (11) omitted to assess intra-examiner agreement that was instead the only parameter of reliability considered by Flügge *et al.* (9), whereas Grünheid *et al.* (20) limited their evaluation to accuracy (Table 2). Additionally, the use of *t*-test or of correlation coefficients to statistically analyse inter- and intra-observer agreement, as done in the studies by Naidu and Freer (1), and Wiranto *et al.* (11) (Table 2) has recently been criticized and the Bland–Altman plot has been proposed as a better method to determine reliability (28, 29). Such method was applied only in the article by Grünheid *et al.* (20) (Table 2). Therefore, the need for a standardization of the methods to assess measurements' reliability also emerged from this literature review.

Additionally, it is worth mentioning that linear measurements, such as tooth width and arch length, were considered in the comparisons between digital and plaster models. However, it remains to be verified whether interarch measurements of diagnostic relevance, such as overjet, overbite, molar relationship, canine relationship, can be accurately recorded on virtually occluded models. Such evaluation would also test the dependability of the virtual bite registration procedure. Indeed, only one study has assessed the accuracy of the optical bite registration in the clinical setting (30), and the *in vitro* data currently available on this issue are also scarce (31).

When considering the sampling methods followed in the clinical studies on digital impressions, they appear questionable and possibly introducing a selection bias (Table 2) (14, 15). By limiting sample collection to only adult subjects in complete permanent dentition, a defective evidence, completely lacking data on children, has so far been provided. The neglected information would instead be clinically relevant, as a major percentage of orthodontic patients is represented by children. Children could

indeed most benefit from the optical technology for impression taking, that avoids the intra-oral use of materials possibly evoking gag reflexes (17). Nevertheless, the compliance of children with the new methods of digital impressions is still largely unexplored. Particularly, children's response to the powdering procedure deserves investigation. Preliminarily spraying the dental arches with an opaque powder is requested for the use of some marketed scanners, yet the procedure is considered advisable with any scanning device, in order to enhance the quality of images (8). As saliva contamination would impair proper powdering, the use of check retractors and a tongue guard is probably advantageous in small patients (8). Such children-specific issues have not yet been assessed in clinical research and should be addressed in future investigations. Still with regard to the use of powder, it was interesting to notice that in the only one study where patients' preference for conventional impressions over intraoral scans was reported, a scanner that requires powdering had been used (20). Also, the ease of access to all the dental arches areas of children should be verified for the several available scanners. The wands of the currently marketed devices are indeed quite different in size and shape.

Still with reference to the sampling method, it should be noticed that restricting the investigation to Class I occlusions (9), or excluding severely crowded dentitions (11) limits the generalizability of the collected evidence. In future research, the accuracy of intraoral scanning should actually be tested also in the presence of malocclusions, perhaps featuring severely tipped or overlapped teeth, to provide an overall evaluation of the clinical effectiveness of the new technology.

The assessment of time requirements for full-arch scanning is relevant to determine whether digital technology is practical for routine impression taking in orthodontics. The scanning times measured in the published studies varied largely (11, 16–20). Some protocols included also the steps preliminary to image acquisition (11, 19, 20) and/or the bite registration procedure (17, 19). It is plausible that such variability in the study methods contributed to the large discrepancies in time measurements seen among the investigations. The methodological inconsistency of the available studies prevented the collection of a conclusive evidence regarding time efficiency of full-arch scanning. Therefore, in future studies, for comparative purposes among scanners and with the conventional method, it would be advisable to precisely define what procedural steps should be included in the computation of the scanning time.

Conclusions

In only eight published studies complete-arch scans had been performed intraorally and in just four of them data on validity, repeatability, reproducibility of digital measurements were provided. Only two of all the marketed scanners have been investigated under clinical conditions. According to the QUADAS tool (14, 15), no study was adequate with regard to the sampling method, as sample collection was limited to subjects in complete permanent dentition.

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