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A systematic review of clinical trials on digital impression of prepared teeth

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ABSTRACT

Aim The purpose of this review is to verify, in the existing literature, how many clinical studies have been conducted by performing intraoral digital impressions on prepared teeth.
Materials and methods An electronic search was performed through Pubmed database, and the keywords were: "digital impression", "intraoral digital impression", "NOT implant". The selection process started with a primary screening based on titles and abstracts. Afterward, full-texts were carefully read. Only studies in accordance with the inclusion criteria were selected.
Results Only 16 studies dealing with the required criteria were included. Most of the studies evaluated marginal fit, impression time, dentists' and patients' evaluation of impressions and clinical outcome of CAD/CAM (Computer-aided design/Computer- aided manufacturing) fabricated single crown and multiple-fixed dental prosthesis using intraoral digital impression and the conventional impression.
Conclusion In the literature there are only few *in vivo* clinical studies regarding digital intraoral impressions on prepared teeth. More studies about how the experience of the operator affects the accuracy of digital impression, and about the learning curve are needed, in order to provide clinical evidence on the practical use of this technology.

KEYWORD Clinical trials, Digital impression, Intraoral digital scanner, Prepared teeth.

INTRODUCTION

Digital impression technology and CAD/CAM systems appeared for the first time in dental practice in the early 1980s and found their application in many areas of dentistry such as restorative, orthodontics and prosthesis (1-5).
CAD/CAM technology is based on three steps: data acquisition, data processing and digital fabrication process. Data acquisition consists in obtaining a "virtual master model" either with intraoral scanners (direct digitalization) directly in the dental practice, or with laboratory scanners (extraoral digitalization), getting the information from a master model, after casting the conventional dental impression. Thanks to the rapid progress in optical technology, intraoral scanners are gaining more and more credit among professionals.
The development of digital methods has brought several advantages including real-time display of impression, improved patient acceptance, reduced gag reflex, reduction in chair time for tray selection, cast setting time, disinfecting of the cast, and transport to the laboratory, reduced distortion of impression materials, 3D previsualization of tooth preparations, potential cost and time effectiveness, minimal invasiveness, simplified process, instant feedback, easy transfer of digital data for communication with professionals and patients and storage requirements (6-13). The creation of a digital model starting from an intraoral scan is a real advantage because it allows to eliminate the inaccuracies related to gypsum material dimensional changes and handling (9, 14), and to create prosthetic products that exhibit the same or better clinical results compared to fixed-dental prosthesis fabricated from conventional workflow. In fact, there are many *in vitro* studies that assess impression time, clinician's assessments of impressions, marginal fit, impression accuracy, and clinical outcomes of fixed dental prostheses produced with CAD/CAM systems. Flügge et al. (15) stated that intraoral digital impression was less precise than the one performed on model, maybe due to patient-related factors such as movement, limited intraoral space, intraoral humidity, and saliva flow.

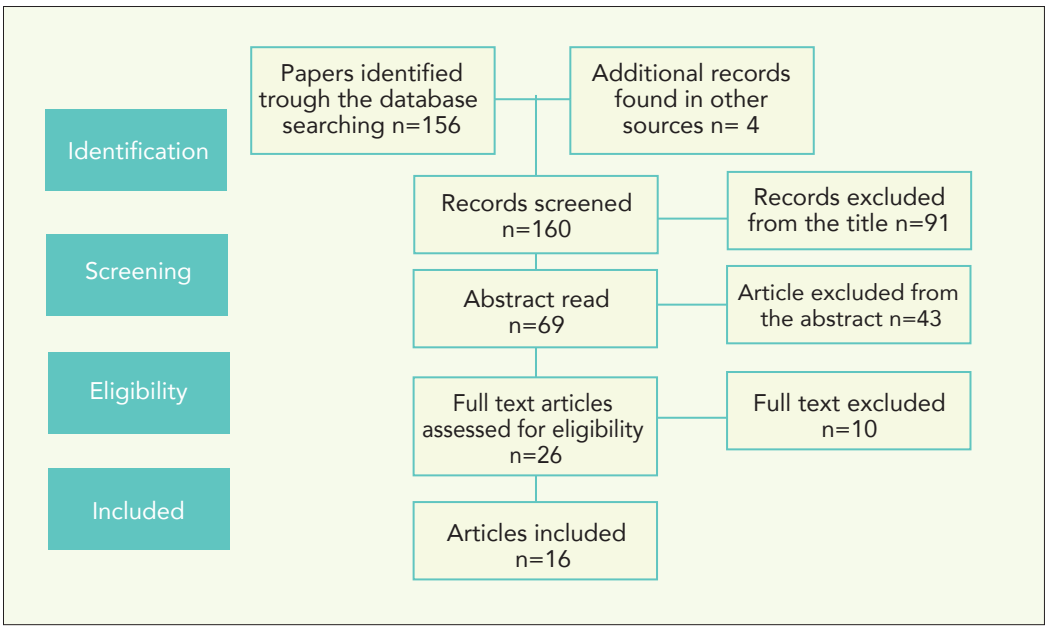

FIG. 1
Flow diagram of paper selection.

This shows that it is important to collect data obtained from *in vivo* studies. In a recent review, Mangano et al. (16) report that there is no evidence in literature whether one scanning strategy is better than other ones and consequently this aspect remains open and to be clarified.
Use of the intraoral scanner (IOS) system will increase in dental practice, especially in prosthetic area, therefore it is important to provide clinical evidence on the practical use of this technology.
The purpose of this review is to verify, in the existing literature, how many clinical studies have been conducted by performing intraoral digital impressions on prepared teeth and evaluate their conclusions.

MATERIALS AND METHODS

An electronic search was performed through Pubmed database, and the keywords were: "digital impression", "intraoral digital impression", "NOT implant".
The following items were screened based on titles, abstract and full text.
Inclusion criteria: *in vivo* study, intraoral digital impression, prepared teeth.
First analysis based on titles eliminated articles that did not refer to these requirements.
Then, the abstracts were analyzed and if it was clear from the abstract that the study did not deal with intraoral digitalization on prepared teeth, or if it was conducted under *in vitro* condition, it was excluded.
The full-texts of selected articles were examined more closely and evaluated based on inclusion criteria. A further investigation was conducted through Google to verify the same query items used in the Pubmed search. Only relevant papers were added to this review (Fig. 1).

RESULTS

Entering the above mentioned keywords, a total of 160 papers were found through Pubmed and Google searches. The selection process started with a primary screening based on titles and abstracts. Afterward, full-text were carefully read, only 16 studies dealing with the required criteria were included (Table 1).
Most of the studies evaluated marginal fit (17-28), dentists and patients evaluation of impressions and clinical outcome of CAD/CAM fabricated fixed dental prosthesis using intraoral digital impression and the conventional impression (23)(27)(29). Only one study (30) reported data on accuracy of both impression techniques in terms of "trueness" and "precision" under *in vivo* conditions.
The included papers were related to different prosthetic restorations: fourteen studies deal with single crown (17-30), and multiple-unit tooth-supported restorations (17).
For single crown, scan protocols consisted of a quadrant scan capturing the prepared tooth, the opposite quadrant scan, and the intercuspation where optically scanned. Scan protocols for multiple-unit fixed dental prostheses provided a full-arch scan of the prepared teeth, the antagonist arch and occlusal relationships.
Three studies reported differences in conventional and digital impression time (17, 23, 29).
Three of the selected papers compared the performance of different intraoral digital scanners (25, 26, 29). More recently two randomized clinical trial (RCT) showed the limitations on reproducing the finishing margins when are closer than .5 mm to the gingival tissues (31, 32). All the patients included in these studies needed prosthetic

Authors	Partecipants	Preparations	Location of the finish line	Scanner	Main topic
Ahrberg et al. (17)	25	Chamfer	Gingival level or 0.5 mm subgingival	Lava C.O.S.	Marginal and internal fit, time IOS vs conventional impression
Syrek et al. (18)	20	Round shoulder	Gingival level or subgingival	Lava C.O.S	Marginal fit IOS vs conventional impression
Zarauz et al. (19)	20	Chamfer	Gingival level or 1 mm subgingival	iTero	Marginal and internal fit IOS vs conventional impression
Berrendero et al. (20)	30	Chamfer	Gingival level or 1 mm subgingival	TRIOS	Marginal and internal fit IOS vs conventional impression
Pradìes et al. (21)	25	Chamfer	Gingival level or 1 mm subgingival	Lava COS	Marginal and internal fit IOS vs conventional impression
Rodiger et al. (22)	20	Chamfer	Gingival level or 1 mm subgingival	TRIOS	Marginal and internal fit IOS vs conventional impression
Gjelvold et al. (23)	14	Chamfer	Supragingival, gingival level, subgingival	TRIOS	Time, dentists' and patients' assessments, marginal fit IOS vs conventional impression
Scotti et al. (24)	15	Chamfer	Gingival level or 0.5 mm subgingival	Lava COS	Marginal and internal fit IOS
Boeddinghaus et al. (25)	24	Chamfer	Gingival level or 0.5 mm subgingival	CEREC AC, Omnicam, Heraeus Cara TRIOS, Lava TDef	Marginal fit IOS vs conventional impression
Brawek et al. (26)	14	Chamfer	Supragingival, gingival level, subgingival	Lava COS, CEREC AC	Marginal and internal fit IOS
Sakornwimon et al. (27)	16	Not specified	Gingival level or 0.5 mm subgingival	Lava TDef	Marginal fit, patients' IOS vs conventional impression
Tamim et al. (28)	50	Chamfer	Gingival level or 0.5 mm subgingival	iTero	Marginal and internal fit IOS
Benic et al. (29)	10	Round shoulder	Gingival level or 0.5 mm subgingival	Lava COS, iTero, CEREC Bluecam	Time, patients' and operators' IOS vs conventional impression
Sason et al. (30)	10	Not specified	Not specified	CS 3500	Precision and trueness IOS vs extraoral scans
Ferrari et al. (31)	30	Chamfer	Supragingival	Aadva IOS, Lava TDef, TRIOS	Minimal distance to produce well defined IOS
Mandelli et al. (32)	1	Featheredge	Subgingival	Not specified	Ability to read the sulcus depth IOS vs conventional impression

TABLE 1. Summary of *in vivo* studies about intraoral digital impressions.

restorations in molar or premolar area.

DISCUSSION

Different procedures to evaluate the marginal fit of crowns are well-known and some of them can be used clinically and other ones also under lab conditions. In the lab it is possible to evaluate marginal precision by external observation of the margins, f.i., by SEM (Scanning Electron Microscopy) and/or optical microscope. It is also possible to measure the cement thickness of the crowns at the margins, after cutting the samples and looking inside them by different microscopes (33-35). However, these microscopic procedures can not be used clinically and right now it is not clear enough what clinical parameters can describe success. However, under different anatomical conditions, several studies assessed the value of the marginal discrepancy of crowns.

Under ***in vitro*** conditions, the results seem to be superior to conventional impression techniques due to the avoidance of conventional error sources. Seelbach et al. (36) conducted an *in vitro* experimentation to evaluate the precision of crowns fabricated by using conventional and digital impressions, assessing the accessible marginal inaccuracy and the internal fit; the accessible marginal inaccuracy of the specimen was detected using fit checker and measuring each of the four predefined marks at SEM, the internal fit was determined with a 3D-coordinate measuring system. In a similar study Pedroche et al. (37) evaluated the marginal and internal fit of the Zirconia copings by using the silicone replica technique (33-35). Both these studies reported good marginal fit in dental restorations produced with Lava Chairside Oral Scanner, iTero, TRIOS, and CEREC intraoral scanners.

It is clear from this review that, even for in vivo studies, the comparison of the marginal fit of single-crowns and fixed dental prostheses obtained using intraoral and extraoral method, has been investigated. Marginal gap evaluation is very important, in order to prevent clinical situations such as exposition of abutment teeth, aggregation of plaque at the gingival margins, leading to periodontal problems and secondary caries (38-42). For the clinical evaluation of the marginal and internal accuracy of restorations, the replica technique of the intermediate space between the inner surface of the crown and tooth surface, combined with light microscopy has been shown to be the only procedure that can be used (33-35). In a study by Ahrberg et al. (17), 25 patients with indications for indirect restorations, seventeen single all-ceramic zirconia crowns and eight 3-unit fixed-dental prostheses (FDPs) were fabricated by direct digitalization and indirect digitalization and selected for evaluation of the fit under clinical conditions. Preparation of the abutment teeth was performed with chamfer finish lines located at a gingival level or at 0.5-mm subgingival level. The results showed significant differences between the types of methods applied. Zirconia frameworks of single crowns and three unit FDPs fabricated from computer-aided impressions showed a mean of 61.08 µm (±24.77 µm), while those fabricated from conventional impressions 70.40 µm (±28.87 µm). It demonstrated that a significantly better marginal fit is noted in intraoral direct digitalization. The marginal values for both methods were within the range of clinical acceptance according to Mclean et al. (38). In a similar comparative study protocol by Syrek et al. (18), twenty patients with indication for a single all-ceramic crown received one crown fabricated on the basis of direct digitalization with Lava COS and a second crown from a conventional impression. Teeth preparation margins were half subgingival and half paragingival. The study revealed a median marginal gap in the digital impression group of 49 µm and a gap of 71 µm in the conventional impression group. These studies are in agreement with the outcomes of others clinical studies dealing with computer-designed restorations supported by natural teeth. Zarauz et al. (19) assessed the marginal fit of single-crowns resulting from a conventional impression and intraoral digital scan with iTero using stereomicroscopy. The preparation margin was placed at the gingival level or not exceeding 1 mm of subgingival depth. Measurements were taken at different landmarks: margin, chamfer angle, axial, crest, and occlusal fossae. The fit values were significantly affected by impression technique, in fact computer-aided impression group had a better fit. Even Pradies et al. (21) research found better results in terms of marginal gap with Lava Chairside Oral Scanner than those obtained from conventional impressions. As well as in Zarauz study, chamfer preparations were placed equigingival and in any case not exceeding a subgingival depth of 1 mm. It follows from the clinical results that intraoral digital impressions as the first step of the digital workflow could improve the marginal adaptation of ceramic crowns.

Others published researches revealed that there are no statistically significant differences in the marginal fit between the different techniques (20,22,23,27). Berrendero et al. (20), compared marginal fit values of all-ceramic single crowns fabricated from conventional impression and intraoral digital impression whit TRIOS. Teeth were prepared with a chamfer finish line placed juxtagingivally or 1 mm subgingivally. Replica film thickness was detected by means of a stereomicroscope at seven sites: buccal margin, buccal axial, buccal crest, lingual margin, lingual axial, lingual crest and fossae. The results confirmed that there was no statistically significant difference in the marginal fit of both techniques. In two similar studies, Rödiger et al. (22) and Gjelvold et al. (23) stated the same conclusions using the same introral scanner. Sakornwimon et el. (27) still compares the conventional and digital technique using 3M True Definition scanner. They demonstrated that the two methods did not differ, and both provided prosthetic restorations with an acceptable marginal fit.

Marginal fit values from different systems were compared in three studies (25,26,29). Boeddinghaus et al. (25) based their research on the comparison between three different intraoral scanners, Sirona CEREC AC Omnicam (OCam),

Heraeus Cara TRIOS and 3M Lava True Definition (TDef) and one conventional impression method (model was scanned with a standard laboratory scanner). The marginal gap was 88 µm (68-136 µm), for the TDef, 112 µm (94-149 µm) for the Cara TRIOS, 149 µm (114-218 µm) for the OCam, and 113 µm (81-157 µm) for the laboratory scanner. They found a statistically significant difference between OCam and the other intraoral systems. However, the values were within the acceptable range. Brawek et al. (26) compared the marginal fit of single posterior crowns fabricated with two different digital intraoral scanners: Lava COS and Cerec AC (teeth were prepared with a chamfer line, silicone replica was examined using a light microscope). Both systems delivered clinically satisfying results for single crowns. Benic et al. (29), compared Lava COS, iTero, Cerec Bluecam and conventional impressions. The conventional technique and the digital impression with iTero revealed more favorable outcomes than the digital impression with Lava.

A study conducted by Scotti et al. (24) tested the accuracy of Lava COS systems by measuring different landmarks of the preparations (chamfer finish lines were placed juxtagingivally or not more than 0.5 mm subgingivally). They stated that crowns generated with this system presented enough accuracy to be used as an alternative to the conventional impression technique. Tamim et al. (28) assessed the accuracy on metal-ceramic crowns: 50 patients received crowns fabricated from intraoral digital impressions with iTero, and clinical evaluation showed good results within acceptable range.

Recently, Keeling et al. 2017 (43) described confounding factors that can affect quality of the scanning shots made intraorally; when the margins are located closer than .5 mm to the gingival tissue and/or to the adjacent tooth (teeth), because of the formation of the cloud by the software, the margins will not be detected (catched). Ferrari et al, 2017 and Mandelli et al., 2017 confirmed clinically the above described findings (31,32). Consequently, the clinical studies previously reported are limited on their validity because of the different location of the margins compared to the gingival tissues.

Only a study by Sason et al. (30) evaluated accuracy of both intraoral and extraoral digital impressions in terms of "trueness" and "precision". "Trueness" means a value which is as close as possible to the reference value, while "precision" is the repeatability of the data when different scans are carried out and superimposed between them (44). The results and statistical analysis showed that intraoral scanners had higher precision and trueness values when compared with the extraoral scanners.

Time required for impressions (in the conventional technique and intraoral digital scan) was compared in 3 of the included studies. Benic et al (29) tested three digital systems for the intraoral optical impressions of quadrants and occlusal registration (Lava COS, iTero, and Cerec Bluecam). Then, a conventional unilateral impression (check-bite technique) and the interocclusal record were performed by using PVS. Time difference between conventional impressions and the digital systems was statistically significant, the shortest working time was achieved by the silicone impression, maybe due to the higher operator experience with conventional impressions. In the above mentioned Arhberg et al. (17) study, a quadrant direct scan required on average 5 minutes less time than a complete-arch conventional impression. For 3-unit FPDs, a full-arch scan took on average 1.5 minutes less than a complete-arch conventional impression. Gjelvold et al. (23) stated that the mean impression time were 7:33 ± 3.37 and 11:33 ± 1.56 for digital (Trios) and convention impression respectively.

Patients and operators assessments of digital and conventional impressions using a visual analogue scale (VAS) (8) have been reported in a total of 3 studies (23,27,29).

Sakornwimon et al. (27) stated that patients' preference of digital scan was significantly higher than those with a conventional technique. Benic et al. (29) asked patients to rate comfort of the impression but not statistically significant differences were found between the 3 IOS systems and conventional method. The study also evaluated the perception of the operators among the treatment options in terms of difficulty. Clinicians assessment of difficulty revealed that impressions with conventional technique and iTero impressions were easier than Lava scans. In a study by Gielvold et al. (23) it emerged that the digital impression technique was more convenient for the dentist as well as for the patients.

Powder application is not analysed in the *in vivo* studies included in this review, but it is only mentioned when acquisition technologies require the use of opaque powder to be more performing. In fact, there are not any *in vivo* studies that focus on the use of powder as a strategy to improve the acquisition of a scan.

CONCLUSIONS

Under the limitations of this review and the limited clinical experience on using ios, the following conclusions can be drawn.

1. In the literature there are only few *in vivo* clinical studies regarding digital intraoral impressions on prepared teeth.
2. The available RCT performed different protocols, used different techniques and showed contrasting conclusions and for that any speculation can be avoided.
3. More standardized RCT protocols, focusing on longevity of the restorations, crowns' integration with soft tissues and learning process to achieve a high quality standard are desirable.

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