

# A systematic review about randomized clinical trials on digital impressions on sound teeth

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## ABSTRACT

**Aim** In the dental literature there are a number of studies about digital impressions. They mainly are focused on the reproducibility of the measurements or on the validity, accuracy, trueness and precision of the scans compared with conventional materials, or on the reaction of patients to these new methods. The purpose of this study was to systematically review existing clinical trials reporting about intra oral scanning procedures on sound teeth.

**Materials and methods** PubMed, Cochrane Library and Web of Science databases were electronically searched and enriched by hand searches. The query terms "randomized clinical trials", "in vivo study", "sound teeth", "intraoral scanner", "digital dentistry" combined with the Boolean operators "OR" and "AND" have been used. No language or time limitation was applied. Selection criteria: only randomized in vivo studies where sound teeth had been scanned intraorally were considered.

**Results** Twenty-four out of more than three hundred studies were selected for the review.

**Conclusion** In literature there are enough randomized clinical trials about sound teeth. They report about many clinical aspects.

**KEYWORDS** Digital dentistry, Digital impressions, Intraoral scanner.

## INTRODUCTION

In the last years the use of digital impressions in dentistry has increased because of the progress of scanning systems (1,2,3,4,5).

In everyday life dentists use chairside devices to create digital models instead of using conventional impressions and gypsum casts, with all the advantages that they involves: minimal invasiveness or comfort for the patient, immediate verification of the impression, digital process simplification, instant feedback, easy communication with the patient, colleagues and technicians, reduced impression storage, possibility of a chairside fabrication of custom made removable and fixed appliances, etc. (6). Digital models are used to study cases and make correct treatment plans, or to project prosthesis in a complete digital workflow, which permits the use of new materials that cannot be used with a conventional workflow.

In literature there are a number of studies about precision of different scanners, or about validity, reproducibility and reliability of the scans compared with traditional impression materials. But once these themes are scientifically proved and accepted, scanners will be considered valid and useful for daily dentistry; the learning curve that practitioner might need to achieve a good quality level impression made by intraoral scanner has to be studied.

The present review wants to analyze randomized clinical trials about sound teeth in literature to check which topics have already been analyzed enough and which topics need to be further explored.

In keeping with the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) guidelines for systematic reviews, the research question was then formulated with reference to participants (patients with sound teeth), intervention (full arch or partial digital impressions), and study design (*in vivo* study) parameters of the participants, interventions, comparators, outcomes, and study design (PICOS) method (7).

## MATERIALS AND METHODS

An electronic search of the literature was conducted through PubMed, Cochrane Library and Web of Science, entering the query terms "randomized clinical trials", OR "in vivo study", OR "sound teeth", AND "intraoral scanner", AND "digital dentistry".

No language or time limitation was applied, in order not

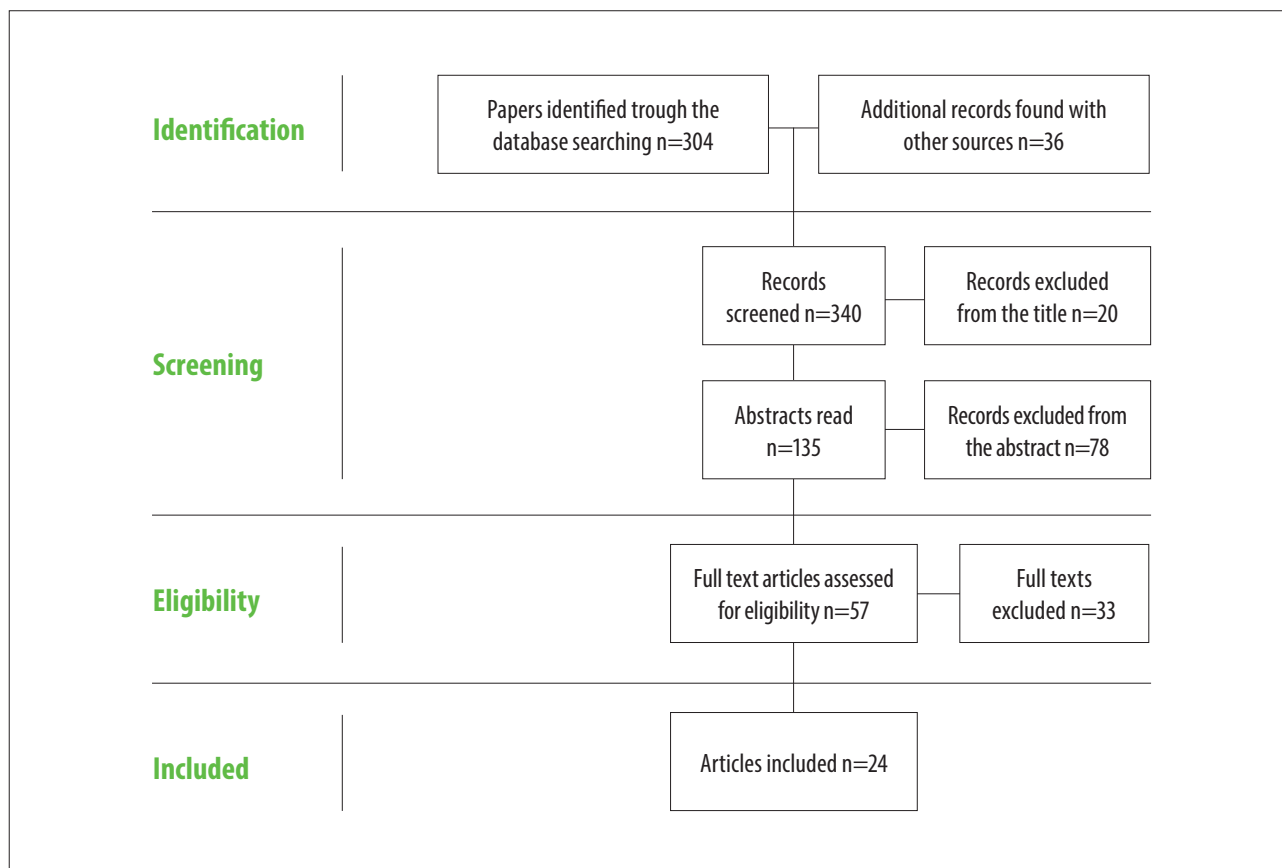


FIG. 1 Selection of articles.

to leave any study out.

Only randomized studies where sound teeth had been scanned intraorally were considered.

The papers were examined in different steps (Fig. 1).

Firstly, all the titles obtained from the research were read and titles that evidently did not refer to sound teeth impressions were excluded.

Then the abstracts of the selected titles were screened and all *in vitro* studies were excluded.

Then full-text articles were carefully read. Only the studies that were relevant to the objectives of the review and satisfied the requirements of the Quality Assessment of Diagnostic Accuracy Studies (QUADAS) checklist (8, 9) were included in the review.

At the end, only randomized clinical studies on sound teeth digital impressions were included.

Papers referenced in the selected studies were added to the reviewed literature if pertinent.

The web was browsed by entering in the Google search box the same query terms as those used in the PubMed.

## RESULTS

Around 300 articles were found from the research on the Pub-Med database and the other steps mentioned.

At first, the titles of these publications were read and those evidently referring to *in vitro* studies, implants or prepared teeth were discarded.

Secondly the abstract of the remaining articles was evaluated, and they were further selected. After an even more in-depth evaluation, and the selection of the studies mentioned as references in those already approved, only twenty-four studies met the criteria of the review (Table 1). In the majority of cases, these studies were about accuracy, trueness or precision (10-23).

Other studies compared digital and conventional impressions (10-16, 19-27).

Five studies were about comfort, time perception and preferences of the patient (24, 25, 27, 28, 29).

Some of them were orthodontic studies (9, 14, 18, 24, 20, 29).

In many cases full arch impressions have been taken (11, 13-17, 30, 31), while in only two studies quadrant impressions have been considered (12, 19).

One study was inspired by a surgical application (31) and one had a gnathological implication (32).

Some papers took into consideration the experience of the operators (27, 29, 30, 33) and other mentioned learning curve (17, 30, 33).

Only two papers (20, 30) considered time as an important factor and only one (13) was about difficulties derived

| Reference | Author      | N of treated patients | Used IOS  | Mean topic investigated  |
|-----------|-------------|-----------------------|---|--|
| 24        | Burhardt    | 38                    | CEREC Omnicam, Lava C.O.S.  | preferences of orthodontic patients                              |
| 25        | Burzynski   | 180                   | iTero, TRIOS  | preferences of patients, comparison with traditional impressions |
| 10        | Camardella  | 28                    | TRIOS color   | accuracy reproducibility of measurements on digital models       |
| 28        | Chalmers    | 43                    | TRIOS   | patient perception   |
| 11        | Ender       | 5                     | Lava T-Def, Lava C.O.S., iTero, TRIOS, TRIOS color, CEREC bluecam 4.0, CEREC bluecam 4.2, CEREC omnicam | comparison between the scanners and traditional impressions      |
| 12        | Ender       | 5                     | CEREC Bluecam, CEREC Omnicam, Cadent iTero, Lava COS, Lava T-Def, Trios, Trios Color                    | comparison between the scanners and traditional impressions      |
| 13        | Flugge      | 1                     | iTero   | precision  |
| 30        | Garino      | 328                   | iTero   | efficiency, scanning times                                       |
| 14        | Grunheid    | 15                    | Lava COS  | accuracy, scan time, patient acceptance                          |
| 31        | Hernández   | 6                     | Lava COS  | interocclusal relationship                                       |
| 32        | Jaschouz    | 15                    | CEREC bluecam   | interocclusal relationship                                       |
| 15        | Kamimura    | 12                    | Lava COS  | inter-operator reproducibility                                   |
| 33        | Kim         | 4                     | iTero, TRIOS  | learning curve   |
| 16        | Kuhr        | 50                    | CEREC Omnicam, Lava T-Def, TRIOS  | comparison between the scanners and traditional impressions      |
| 26        | Lee         | 32                    | iTero, TRIOS  | comparison between the scanners and traditional impressions      |
| 17        | Lim         | 1                     | iTero, TRIOS  | trueness, reproducibility, experience                            |
| 18        | Naidu       | 30                    | iOC   | Validity, reliability, reproducibility                           |
| 19        | Ning Gan    | 32                    | TRIOS   | accuracy   |
| 29        | Park        | 24                    | iTero, TRIOS  | operator preferences   |
| 20        | Wiranto     | 22                    | Lava COS  | validity, reliability, reproducibility of linear measurements    |
| 21        | Xie YL      | 5                     | Trios Ortho   | comparison with conventional impressions                         |
| 27        | Yuzbasioglu | 24                    | CEREC Omnicam   | preferences of patients  |
| 22        | Zhang       | 20                    | iTero   | accuracy reproducibility of measurements on digital models       |
| 23        | Zimmermann  | 5                     | Cerec Omnicam Ortho, Ormco Lythos   | comparison with conventional impressions                         |

TABLE 1 The works analyzed.

from intraoral conditions (saliva and limited spacing).

## DISCUSSION

In most of the considered studies it is concluded that intraoral scanners have a clinically acceptable accuracy and excellent reliability and reproducibility (18, 19). Comparing digital intraoral impressions with the conventional ones, Ender concludes that "Digital impression systems had higher local deviations within the complete arch cast; however, they achieve equal and higher precision than some conventional impression materials" as irreversible hydrocolloid material. And that "no advantage in accuracy is gained by digitizing a conventional impression" (11). In another study with the same protocol but on quadrant impression he stated: "The clinical precision of digital quadrant impression model is sufficient to cover a broad variety of restoratives indications".

Conventional materials used to make comparisons were alginate, polyether or polyvinyl siloxane.

In some papers the conventional workflow was used to make a comparison between the reproducibility of the measurements made on digital models with a specific software (as orthocad), and the measurements made on physical models with a digital caliper (10, 18, 20). In Naidu's study measurements of tooth widths are applied to the calculation of Bolton index (18). A similar study is conducted by Wiranto that compares the conventional workflow with the indirect digitization with a CBCT of the model and with a totally digital workflow concluding that both are valid, reliable and reproducible methods (20).

Other studies use conventional materials to compare the patient's preference for conventional impressions or digital ones. Grunheid (14) evaluates time and patient acceptance of full arch scans and finds out that "73.3% of the patients preferred impressions because they were "easier" or "faster"." On the contrary in Burhardt's and Yuzbasioglu's studies patients prefer digital impressions (24, 27).

The practical aspect is also evaluated by Park (29) but from the operator's point of view. He uses questionnaires asking about the difficulty of use, patient discomfort, awareness, preference, and clinical usefulness of two intraoral scanners (iTero and Trios) comparing them. This paper focused the attention on a singular point: appropriate training can change the operator's perceptions on the efficiency of intraoral scanners positively.

In other publications the importance of training is considered: Garino conducts a study in which operators have the same training and similar skills (30), Lim (17) and Kim study the changes of scanning accuracy and time respectively, with repeated scanning experience in operators with almost three years of working experience. Kim concludes that "scanning time was influenced by clinical experience", it decreased after repeated scanning, while scanning proficiency increases (33). A

limitation of Kim's study is that operators did only ten digital impressions and this number of session was too short to reach a plateau: the learning curve presented is incomplete because scanning time decreased until ninth and tenth sessions, so that it can only be supposed that with continuous practice a plateau would be reached. All these studies were on hygienists not dentists or dentistry students.

Other aspects of intraoral digital impressions have been taken into consideration: Kamimura studies the interoperator reproducibility and asserts that "interoperator reproducibility with a digital impression technique may be better than that of a conventional impression technique and is independent of the clinical experience of the operator" (15). This is one of the best advantages of intraoral scanners: make the operator's experience almost irrelevant on the quality of scans so that even a young inexperienced operator can be able to take a good quality impression.

Only in Yuzbasioglu's paper operators have no previous experience and times of scanning with Cerec (Omnicam, Sirona) are compared. "The mean overall treatment time of the digital impression technique was  $248.48 \pm 23.48$  s (27). The mean time for entering patient information was  $19.08 \pm 3.57$  s, and the mean time for entering the laboratory prescription time was  $13.63 \pm 1.98$  s. The mean digital impression time for the upper and lower jaws was  $98.94 \pm 10.56$  s and the mean bite scan time was  $14.68 \pm 3.82$  s." (27).

Time is also considered by Garino (30) who notes that once experience has been gained, the time needed to make a full intraoral scan with itero is 10-11 minutes, and by Wiranto who focuses his analysis on the measurements on plaster and digital models mentions the use of powder and time and techniques needed to prepare teeth to the scan: "for making an intraoral scan, the tooth surfaces were first dried and coated with a thin layer of titanium oxide powder; the process of powder coating the dentition takes 1 minute. The maxillary and mandibular dentitions were scanned separately, and then a scan of the teeth in occlusion was made" (30).

Few studies look at clinical practice, Flugge considers specifically that "intraoral conditions (saliva and limited spacing) contribute to the inaccuracy of a scan" (13).

Other applications of intraoral scanners are also interesting, in particular two studies were different from the others selected for this review: Jaschouz studies how the habitual intercuspation of patients varies with the position of the patient and at different times (32). Meanwhile Hernandez shows how digital models can be used in combination with CBCT to create a virtual patient and to study the intermaxillary relationship "to obtain the intermediate splint by CAD-CAM technology (computer aided design, computer aided manufacturing) (31) this procedure eliminates the need for dental impressions, simplifies the necessary technical steps and computational work, and reduces the patient's exposure

to ionizing radiation" (31).

However, accordingly with a recent survey made by National Union of Italian Dental Industries (UNIDI), only 5% of European dentists already have an IOS in their practice. That might be in contrast with the RCT results already described. It is highly desirable to have available RCTs with more focus on learning curve to achieve satisfactory IOS impressions from practical and precision point of view.

## CONCLUSIONS

In literature there are enough *in vivo* randomized clinical trials about sound teeth.

A large part of the literature about digital scanning is represented from *in vitro* studies. *In vivo* studies deal with implants or implant surgery applications and fixed prosthesis.

The majority of the reviewed articles concern preferences of patients, comparisons with conventional materials, precision and reliability of the scanners or define their possible applications in the orthodontic or other branches. No study gives the user indications about the learning process and needed time to reach a high standardized quality level of intra oral digital impressions.

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