RESEARCH ARTICLE

Orthodontics & Craniofacial Research   WILEY

Comparison between digital and conventional impression techniques in children on preference, time and comfort: A crossover randomized controlled trial

Carlo Bosoni[1] | **Michele Nieri[2]** | **Debora Franceschi[2]** | **Bernardo Quiroga Souki[3]** | **Lorenzo Franchi[2,4]** | **Veronica Giuntini[2]**

[1]Graduate Orthodontic Program, Department of Experimental and Clinical Medicine, The University of Florence, Florence, Italy

[2]Department of Experimental and Clinical Medicine, The University of Florence, Florence, Italy

[3]Graduate Program in Orthodontics, Department of Dentistry, Pontifical Catholic University of Minas Gerais, Belo Horizonte, Brazil

[4]Thomas M. Graber Visiting Scholar, Department of Orthodontics and Pediatric Dentistry, School of Dentistry, The University of Michigan, Ann Arbor, Michigan, USA

Correspondence
Lorenzo Franchi, Department of Experimental and Clinical Medicine, Università degli Studi di Firenze, Firenze, Italy.
Email: lorenzo.franchi@unifi.it

Abstract

Objective: To compare the conventional alginate impression and the digital impression taken with an intraoral scanner of both dental arches in children, using a randomized crossover design.

Trial Design: This is a monocentric, controlled, superiority, randomized, crossover, open study.

Methods: Twenty-four orthodontic patients between 6 and 11 years of age underwent intraoral scanning (TRIOS 3; 3Shape) and alginate impression of both dental arches with an interval of 1 week between the two procedures. Participants were recruited from September 2021 to March 2022 and the study was completed in April 2022. Impression time for the two procedures was compared. Patients were asked which one of the two impression procedures they preferred. A questionnaire including Visual Analogue Scale (VAS) for comfort, pain, gag reflex and difficulty in breathing, was administered to the patients.

Results: Eighteen out of 24 patients preferred digital impression (75%, 95% confidence interval [CI]: 55% to 88%; $P = .014$). Scanning time was significantly shorter than alginate impression time (difference −118 seconds; 95% CI: −138 to −99; $P < .001$). Comfort was significantly higher for digital impression (difference 1.7; 95% CI: 0.5 to 2.8; $P = .007$). There was no difference in pain (difference −0.2; 95% CI: −1.5 to 1.0; $P = .686$) while gag reflex and breathing difficulties were smaller for digital impression (gag reflex difference −2.5; 95% CI: −4.0 to −0.9; $P = .004$ and breathing difficulties difference −1.5; 95% CI: −2.5 to −0.5; $P = −.004$).

Conclusions: Digital impression is preferred by children aged 6–11 years and it is significantly faster in acquisition time than conventional alginate impression.

Registration: The study was registered on ClinicalTrials.gov with registration number NCT04220957 on January 7th, 2020 (https://clinicaltrials.gov/ct2/show/NCT04220957).

1 | INTRODUCTION

The impression is a necessary step for the orthodontic diagnosis.[1] Plaster models of dental arches have been used traditionally to obtain 3D diagnostic records. Digital impression has been introduced recently by means of intraoral optical scanners that produce a three-dimensional image of the teeth.[2–4] This overcomes the problem of pouring and trimming plaster casts, thus eliminating a major component of laboratory work and the need to store the models. Conventional cast analysis allows the clinician to evaluate the location and severity of dental crowding and to evaluate tooth-size relationships within the dental arches.[5] This analysis now can be done more easily by means of software for virtual dental models.[6–8] Semi-automated software can be used to measure the arch length and Bolton discrepancies, and multiple virtual treatment setups can be performed with minimal effort.

Since digital models can be a reliable alternative to stone casts in analysing mixed[6] and permanent dentitions,[7] few studies have compared the conventional alginate impression with the digital impression with intraoral scanners in growing patients.[9–12] These studies have shown that digital impression could have some advantages in terms of greater satisfaction and less discomfort for the paediatric patient with respect to conventional alginate impression. Only one study was randomized and analysed patients between 10 and 17 years.[9] To our knowledge, no previous RCT compared preference, time and comfort between conventional alginate impression and digital impression in orthodontic patients between 6 and 11 years.

The objective of the present study was to compare the conventional alginate impression with the digital impression of both dental arches in orthodontic patients between 6 and 11 years of age with a randomized crossover design. In particular, the preference, comfort, impression time, pain, gag reflex and breathing difficulty were analysed.

2 | MATERIALS AND METHODS

The experimental design followed the Consolidated Standards of Reporting Trials (CONSORT) statement and extension checklist for reporting within-person randomized trials.[13,14]

2.1 | Ethics statement

The principles outlined in the Declaration of Helsinki on clinical research involving human subjects were adhered to. The study was approved by the Paediatric Ethics Committee of the Region of Tuscany, Italy (approval number 07/2020).

2.2 | Protocol registration

The study was registered on ClinicalTrials.gov with registration number NCT04220957 in January 2020 (https://clinicaltrials.gov/ct2/show/NCT04220957).

2.3 | Trial design

This is a monocentric, controlled, superiority, randomized, crossover, open study. Two impression procedures of both dental arches (conventional alginate and digital with intraoral scanner) were compared in two sessions with an interval of 1 week between the two procedures.

2.4 | Participants

The subjects were enrolled in the study at the Orthodontic Clinic of the Careggi University Hospital, in Florence, Italy by an operator (LF). To be included in the study, patients had to be aged between 6 and 11 years and not in treatment with fixed orthodontic appliances. Patients were included if they were not in treatment or if they were in treatment with removable appliances.

Exclusion criteria were:

1. Non-compliant patients;
2. Patients with syndromes or systemic diseases;
3. Patients suffering from cleft lip and palate.

Patients' parents signed an informed consent before starting the trial.

2.5 | Interventions

A single experienced operator (VG) performed both impression procedures of the dental arches. Conventional impressions of both arches were taken with alginate (Orthoprint, Zhermack Sp) with steel impression trays according to the manufacturer's instructions. Red wax (Tenatex, Kemdent) was used for bite registration. The procedure consisted of the following steps: test of the tray, preparation of the alginate for the lower impression, impression of the lower arch, preparation of the alginate for the upper impression, impression of the upper arch and bite registration with red wax. The alginate was hand-mixed with tap drinking water. The digital impressions were made with the TRIOS 3 intraoral optical scanner (3Shape) following the procedure reported by the
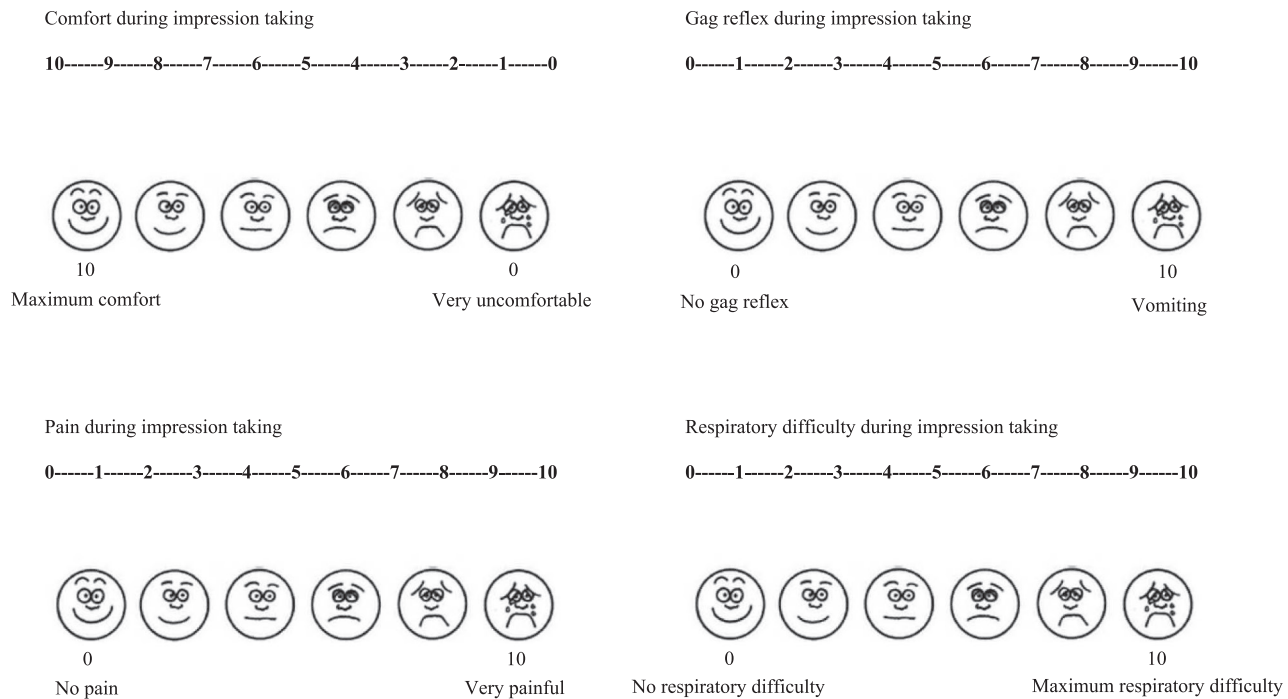
Comfort during impression taking

10------9------8------7------6------5------4------3------2------1------0

10
Maximum comfort

0
Very uncomfortable

Gag reflex during impression taking

0------1------2------3------4------5------6------7------8------9------10

0
No gag reflex

10
Vomiting

Pain during impression taking

0------1------2------3------4------5------6------7------8------9------10

0
No pain

10
Very painful

Respiratory difficulty during impression taking

0------1------2------3------4------5------6------7------8------9------10

0
No respiratory difficulty

10
Maximum respiratory difficulty

FIGURE 1 Visual Analogue Scale with Wong–Baker scale to evaluate patient comfort, pain, gag reflex, and breathing difficulty in the two impression methods.

manufacturer. In the lower arch, the occlusal, lingual and vestibular surfaces were scanned in sequence. In the upper arch, the occlusal, buccal and lingual surfaces were scanned in sequence. Finally, bite registration was taken. The two impression procedures of both dental arches (conventional alginate and intraoral scanning) were carried out in two sessions with an interval of 1 week between the two procedures.

Another operator (CB) hand-mixed the alginate and registered impression time for both procedures.

2.6 | Outcomes

The primary outcome of the study was the patient's preference for one of the two procedures. Secondary outcomes were duration of the procedure, comfort, pain, gag reflex and difficulty in breathing.

Patients were asked which one of the two impression procedures they preferred. In addition, a questionnaire including VAS for comfort, pain, gag reflex and difficulty in breathing was provided to the patients. The VAS consisted of a scale with a score from 0 to 10 (Figure 1). In the case of comfort, 0 corresponded to very uncomfortable while 10 to maximum comfort. To facilitate interpretation, the Wong-Baker Scale was also used.[15] In case of pain, 0 corresponded to no pain while 10 to very painful. For gag reflex, 0 corresponded to no gag reflex while 10 to vomiting. For breathing difficulty, 0 corresponded to no respiratory difficulty while 10 to maximum respiratory difficulty. Similar VAS scores have been used already in a previous study.[10] Finally, the

duration of the impression procedure was recorded with a digital chronometer.

2.7 | Sample size

Considering a null hypothesis for a proportion of 50% in the preference between the two treatments and an alternative hypothesis of 80%, with alpha set at 0.05, a power of 80% and a dropout rate of 10%, 24 patients were required.

2.8 | Randomization

The order of the two procedures was block randomized so that 12 patients received as first impression procedure the conventional alginate and 12 patients received as first impression procedure the intraoral scanning. The randomization list was computer-generated by the statistician (MN) and hidden inside numbered, opaque and sealed envelopes that were opened at the time of impression taking. The second impression procedure was performed after 1 week. Patients were enrolled by one operator LF and they were assigned to the impression procedure by another operator VG.

2.9 | Blinding

Both the operator who took the impressions and the patients could not be blinded as for the impression procedure.

2.10 | Statistical methods

Descriptive statistics were performed for all variables (frequency and percentage for qualitative variables and mean and standard deviation for quantitative variables). For the primary endpoint variable (impression procedure preference) the test was performed for one proportion and the 95% confidence interval [CI] was calculated using the Clopper-Pearson method.

As for the secondary endpoint variables, duration of the procedure, comfort, pain, gag reflex, breathing difficulty, the two procedures were compared with the t-test for paired data. McNemar test was used to evaluate complications.

For quantitative variables, the W Shapiro–Wilk test was performed to test for normality of the data. In case of statistical significance of the test, a non-parametric sensitivity analysis was performed using the Wilcoxon test. Statistical analysis was carried out according to the intention-to-treat method. All statistical tests were performed with JMP 13.0 (SAS Institute Inc.) using a level of statistical significance of .05.

3 | RESULTS

Twenty-four participants were randomized to the two impression procedures (Figure 2).

Participants were recruited from September 2021 to March 2022 and the study was completed in April 2022.

There were no dropouts and there were no deviations from the planned protocol.

The mean age of the participants was 8.8 years (SD 1.0) (min 6.7 years; max 10.7 years). There were 13 females and 11 males.

Twelve participants were allocated to alginate impression as first impression procedure (Alginate Group) and 12 participants were allocated to digital impression with the intraoral scanner as first impression procedure (Scanner Group).

Six patients preferred alginate impression (25%, 95% CI: 12% to 45%) while 18 patients preferred digital impression (75%, 95% CI: 55% to 88%). This difference in preference was statistically significant ($P =.014$).

The differences between the two impression procedures as for scanning time, comfort, pain, gag reflex and breathing difficulty are reported in Table 1.

Impression time was significantly shorter for the Scanner Group (difference −118; 95% CI: −138 to −99; $P <.001$). Difference in comfort was statistically significant favouring the Scanner Group (difference 1.7; 95% CI: 0.5 to 2.8; $P =.007$). Differences in gag reflex and breathing difficulties also were significant favouring the Scanner Group (difference for gag reflex −2.5; 95% CI: −4.0 to −0.9; $P =.004$, difference for breathing difficulties −1.5; 95% CI: −2.5 to −0.5; $P =.004$). On the contrary, no differences in pain were found between the two groups (difference −0.2; 95% CI: −1.5 to 1.0; $P =.686$).

There were two vomiting-related complications in the Alginate group (8%) and none in the Scanner group ($P =.157$).

The W Shapiro–Wilk test for normality was significant for pain and for gag reflex. The P values of the Wilcoxon tests ($P =.424$ for pain and $P =.003$ for gag reflex), however, were similar to those of the t-test for paired data.

4 | DISCUSSION

The aim of this study was to compare the conventional alginate impression with the digital impression of both dental arches in orthodontic patients between 6 and 11 years, an age interval that has not been analysed in the literature yet. As reported in a recent systematic review,[4] intraoral scanners appear to be a promising new resource in the hands of orthodontists, as they have advantages in terms of experience and individual preferences.[4] In the present study, 18 out of 24 children with an age between 6 and 11 years, preferred the digital impression versus conventional impression with alginate. This outcome may be related to the lower invasiveness of the digital impression compared to the conventional impression confirmed by the more favourable results in comfort, gag reflex and breathing difficulties. In addition to the reduced invasiveness, there was also a significant reduction in impression time. No difference between the two impression procedures was recorded for pain.

Several studies have been conducted on the preference between intraoral scanning and conventional impression in growing subjects (younger than 18 years).[9-12] The results of the present study are in agreement with Mangano et al,[11] Yilmaz and Aydin[10] and Burhardt et al[9] that reported a greater preference for intraoral scanning (100%, 75% and 51%).

As for the duration of the impression procedure, in our study scanning time was significantly shorter with respect to alginate impression time. Scanning of both arches and bite registration took about 3 minutes on average while impressions of both arches with alginate and bite registration with wax required about 5 minutes on average. A difference of about 2 minutes between the two impression procedures could have a clinically relevant impact, especially in children. On the contrary, similar studies in the literature[9-11] did not show a shorter time for digital impression when compared to conventional impression. In particular, Yilmaz and Aydin[10] did not find a significant difference in total impression time between the two procedures, while Burhardt et al[9] Mangano et al[11] reported a significantly shorter time for conventional impression with alginate. This outcome can be explained by the fact that both studies used a relatively older technology for digital impression. In addition, patients included in the present study were between 6 and 11 years old, at a stage of dentition prior to the eruption of the second molars. The absence of the permanent second molars, in an area difficult to reach by the scanner tip, could have contributed to speeding up the scanning procedure.[10]

In the present study, a statistically significant difference between the two impression procedures favouring the Scanner Group in terms of comfort, gag reflex and breathing difficulty, was recorded. Two studies found similar outcomes for these

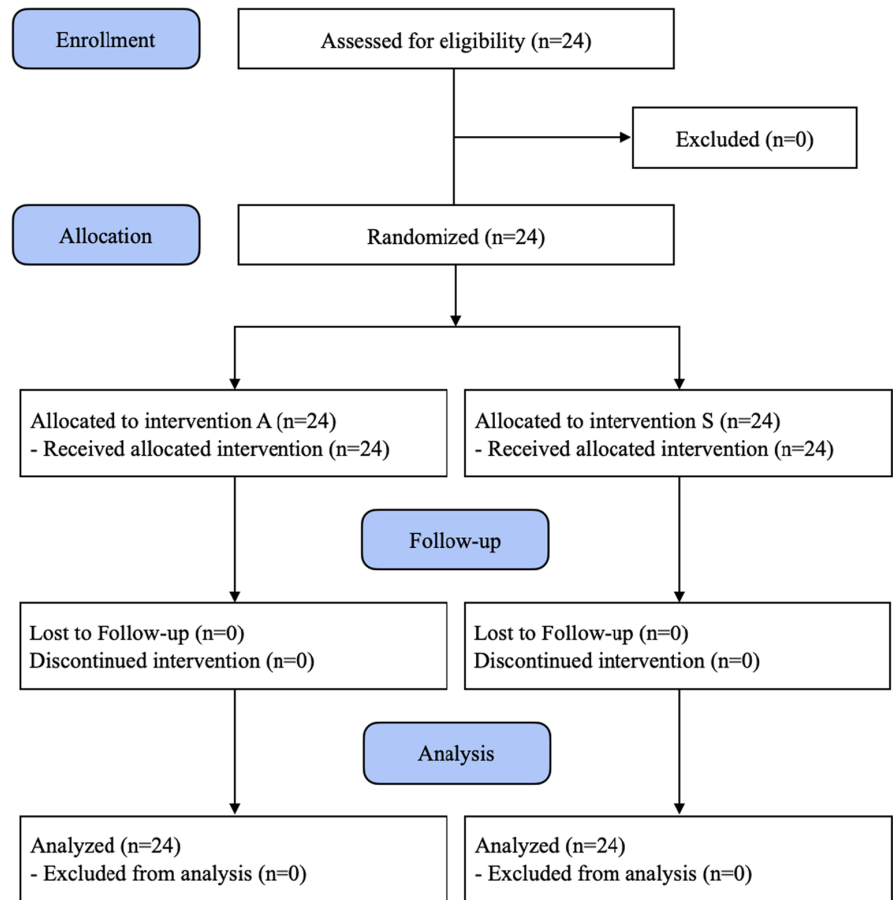**FIGURE 2** Consort 2010 flow diagram. A, Alginate Group; S, Scanner Group.

TABLE 1 Impression time (duration), comfort, pain, gag reflex, and breathing difficulty for the two impression procedures.

Variable	Alginate group (N = 24) Mean (SD)	Scanner group (N = 24) Mean (SD)	Difference	95% CI	P-value
Duration (seconds)	301 (31)	183 (38)	−118	−138; −99	<.001
Comfort	6.6 (2.7)	8.3 (1.8)	1.7	0.5; 2.8	.007
Pain	1.7 (2.5)	1.5 (2.5)	−0.2	−1.5; 1.0	.686
Gag reflex	2.5 (3.7)	0.1 (0.4)	−2.5	−4.0; −0.9	.004
Breathing difficulty	2.4 (2.3)	0.9 (1.8)	−1.5	−2.5; −0.5	.004

Abbreviations: CI, confidence interval; SD, standard deviation.

variables.[11,12] Another study[10] found significant differences in comfort and gag reflex (favouring intraoral scanning) though non-significant differences were reported in breathing difficulty between the two procedures.

In the present study, no statistically significant difference was found between the two procedures for pain. A similar outcome was also reported by Yilmaz and Aydin.[10]

A limitation of our study was that previous experience with any kind of impression techniques was not considered. Another limitation of the present study was that no intra-rater agreement of the VAS was performed. A possible additional limitation could be related to the fact that the intraoral scanner used in this study is not the latest version available from the manufacturer. All patients in our sample received intraoral scanning for the first time while they had varying experience with the alginate impression. The results of the present study can be generalized to patients younger than 12 years.

5 | CONCLUSIONS

In children between 6 and 11 years

1. 75% of patients preferred digital impression.
2. Impression with intraoral scanner was significantly shorter than alginate impression.
3. Digital impression performed significantly better than alginate impression in terms of comfort, gag reflex and breathing difficulty.

4. No pain differences were found between the two impression procedures.

5. No statistically significant differences for "vomiting-related" complications between the two impression procedures were found.

AUTHOR CONTRIBUTIONS

CB designed the study and wrote the manuscript. MN generated the randomization list and performed allocation concealment and statistical analysis. DF and BS reviewed the literature and edited the manuscript. LF designed the study and edited the manuscript. All authors read and approved the final manuscript. VG designed the study and performed the interventions.

ACKNOWLEDGEMENT

CONFLICT OF INTEREST STATEMENT

None of the authors have any conflicts of interest.

DATA AVAILABILITY STATEMENT

The data underlying this article will be shared to the corresponding author after reasonable request.

CONSENT FOR PUBLICATION

All authors consent to publication.

ORCID

Lorenzo Franchi https://orcid.org/0000-0002-2072-460X

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