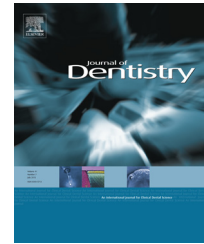


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Clinical evaluation comparing the fit of all-ceramic crowns obtained from silicone and digital intraoral impressions based on wavefront sampling technology

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ABSTRACT

Objective: The aim of this study was to compare the fit of ceramic crowns fabricated from conventional silicone impressions with the fit of ceramic crowns fabricated from intraoral digital impressions.

Methods: Twenty-five participants with 30 posterior teeth with a prosthetic demand were selected for the study. Two crowns were made for each preparation. One crown was fabricated from an intraoral digital impression system (IDI group) and the other crown was fabricated from a conventional two-step silicone impression (CI group). To replicate the interface between the crown and the preparation, each crown was cemented on its corresponding clinical preparation with ultra-flow silicone. Each crown was embedded in acrylic resin to stabilise the registered interface and then cut in 2 mm thick slices in a bucco-lingual orientation. The internal gap was determined as the vertical distance from the internal surface of the crown to the prepared tooth surface at four points (marginal gap, axial gap, crest gap, and occlusal fossa gap) using stereomicroscopy with a magnification of 40 \times . Data was analysed by using Wilcoxon signed rank test ($\alpha = 0.05$).

Results: Internal adaptation values were significantly affected by the impression technique ($p = 0.001$). Mean marginal gap was $76.33 \pm 65.32 \mu\text{m}$ for the crowns of the IDI group and $91.46 \pm 72.17 \mu\text{m}$ for the CI group.

Conclusion: All-ceramic crowns fabricated from intraoral digital impressions with wavefront sampling technology demonstrated better internal fit than crowns manufactured from silicone impressions.

Clinical significance: Impressions obtained from an intraoral digital scanner based on wavefront sampling technology can be used for manufacturing ceramic crowns in the normal clinical practice with better results than conventional impressions with elastomers.

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1. Introduction

Fixed dental prosthesis (FDP) is still mainly produced by casting techniques. The automation of the production process can be achieved by the use of computer-aided design (CAD)/computer-aided manufacturing (CAM) techniques. These techniques are recognised in general industry as a standard workflow in order to obtain high quality products in terms of accuracy and cost production efficiency.^{1,2}

To start with the CAD/CAM workflow a digitalisation process is needed. An optical impression system is a device used to record relevant topographical intraoral surfaces, dental impressions, or stone cast for use in the computer assisted design and manufacturing of dental restorative prosthetics.³ In recent years, various optical impression systems have been developed with which direct impressions could be made in the oral cavity. The most commonly used intraoral dental scanners among others are: Cerec AC (Sirona, Behrnhelm, Germany), Lava Chairside Oral Scanner (Lava COS, 3M ESPE, St Paul, MN, USA), E4D Dentist (D4D Technologies LLC, Richardson, TX, USA), and iTero (Cadent, Carlstadt, NJ, USA). Intraoral scanners play an important role in the development of digital dental technology because they are the first step towards a full digital workflow of prosthetic fabrication.⁴ Intraoral digital impressions improve patient acceptance, reduce possible distortion of impression materials, allow for three-dimensionally (3D) previsualisation of the preparation, decrease potential cost, and increase efficacy.⁵

Also, one of the most significant advances in this field has been the production of high resistance all-ceramic restorations that until today can only be produced with CAD/CAM systems. The popularity of these materials, such as zirconia, has increased significantly in the last decade due to their esthetic, mechanical and biocompatibility properties.^{6–8} In addition to the physical properties and biocompatibility, the predictable production of suitable marginal inter-phases is one of the most important factors for long-term success of restorations.^{9–13} Poor marginal adaptation between the tooth and the restoration increases plaque retention and changes the distribution of the microflora, which can induce the onset of periodontal disease.^{14,15} Poor marginal fit can also cause secondary caries and lead to clinical failure of fixed prosthodontics.¹⁶ Microleakage from the oral cavity may cause endodontic inflammation.¹⁷

Although marginal adaptation is a fundamental factor in the clinical success of the FDPs, there is no consensus on what constitutes a clinically acceptable maximum marginal gap width. The values reported on the maximum acceptable gap in scientific literature range from 50 to 200 μm so, there does not seem to be an objective limit based on scientific evidence.^{10,13,18} At present, many investigators still use the limit established by McLean and Von Fraunhofer of 120 μm .¹⁸

Lava Chairside Oral Scanner (3M ESPE) intraoral scanner is based on the principle of active (optical) wavefront sampling which obtains 3D information from a single lens imaging system by measuring depth based on the defocus of the primary optical system. This device has three sensors, which capture the surface to be scanned from different perspectives. With these three images captured at the same time, 3D surface

patches are generated by proprietary image processing algorithms by using the in-focus and out-of-focus information.¹⁹ With this technology, twenty 3D datasets per second can be captured with over 10,000 data points in each, resulting in over 24 million data points for obtaining an accurate scan of the dental preparation, soft tissues and hard tissues. According to the manufacturer specifications, the high data redundancy resulting from many overlapping pictures together with special image processing algorithms allows us to obtain optimal image quality and high accuracy.

At present, the number of clinical studies that evaluate the fit of the restorations manufactured with an intraoral scanner is still limited.^{11,12,20} The aim of this in vivo prospective study was to evaluate the accuracy of a digital intraoral impression workflow based on the principle of active wavefront sampling technology and to compare it with a conventional silicone impressions workflow by measuring the marginal and internal misfits of the zirconia-ceramic crowns generated with both systems. The null hypothesis was that there is no difference in marginal and internal misfit between crowns obtained from digital and from silicone impressions.

2. Materials and methods

2.1. Study design

This in vivo prospective clinical trial was previously approved by the local ethical committee. The study was conducted in accordance with the Declaration of Helsinki and Good Clinical Practice (GCP). This study included participants aged between 16 and 65 needing a single crown in a posterior tooth, with acceptable standards of oral hygiene, not requiring additional extended treatment of endodontic or periodontics in the study tooth, and who gave informed consent. In contrast, participants with an advanced periodontal attachment loss affecting the mobility of the teeth (mobility degree 1 or higher), severe wear facets or marginal preparation located deeper than 1 mm subgingivally were excluded.

Thirty participants were enrolled into the study and were fitted with 34 zirconia-ceramic single crowns (Lava, 3M ESPE). For each of the 34 teeth in this study, three crowns were made: two crowns for the study, one made by each impression method (intraoral digital impression – IDI and conventional two-step silicone impression – CI); and one crown to be finally cemented produced exactly like the study crown for the CI group. 102 crowns were made in total.

2.2. Tooth preparation

Sixteen molars and eighteen premolars were treated, 15 in the maxilla and 19 in the mandible. All participants received local anesthesia prior to tooth preparation for a ceramic crown. Distinct chamfer finish lines were prepared and placed at gingival level, not exceeding a subgingival depth of 1 mm. The axial reduction of the tooth substance was between 1 and 1.5 mm, in accordance with the remaining hard tissue. Occlusal reduction was approximately 1.5 mm. All internal edges were rounded. The preparation had a divergence angle of around 6%.²¹ After tooth preparation a provisional restoration was

128 placed by using a temporary resin based material (Protemp
129 Crown, 3M ESPE). The participants were then scheduled for
130 refining of the preparation and polishing. A double-cord
131 packing technique was used to allow a correct display of the
132 finish line for the definitive impression (Ultrapak #000 and
133 Ultrapak #00, Ultradent Products, South Jordan, UT, USA). The
134 same retraction double-cord packing technique was used to
135 make both the conventional and the digital impressions. A
136 disposable soft tissue retractor (Optragate, Ivoclar Vivadent,
137 Schaan, Liechtenstein) was placed to retract the cheeks and lips.
138 The mouth was then rinsed with water and air-dried.

139 2.3. Impression protocol

140 One operator randomised the sequence of impression making
141 (conventional versus digital) with a smart phone application
142 (Undecided, Deadmans Production, Wilmington, NC, USA).

143 For the conventional impressions, a polyvinyl siloxane
144 (PVS) material was used in a two-step impression technique
145 (Express 2 Penta Putty as tray and Express 2 Light Body Quick
146 as wash material, 3M ESPE), in rim-lock metal trays. After
147 removal, a trained independent observer inspected the
148 impressions by using 2.8× magnification (ExamVision HD,
149 Akura Medical, Madrid, Spain), verifying that all impression
150 surfaces of the abutments were free of pulls, voids, and air
151 bubbles. The opposite dental arch impression was made with
152 irreversible hydrocolloid impression material (GC Aroma Fine
153 Plus, GC Corporation, Tokyo, Japan), and the occlusal
154 registration with an elastomer material (Imprint 4 Bite, 3M
155 ESPE). The impressions were disinfected and poured with type
156 IV plaster (Fuji Rock, GC Corporation) one hour after mouth
157 removal and sent to our paired laboratory, where the master
158 cast was scanned by means of the extraoral scanner (Lava
159 Scan ST, 3M ESPE).

160 Digital intraoral impressions were made by using an
161 intraoral digital scanner based on wavefront sampling

162 technology (Lava Chairside Oral Scanner, 3M ESPE) according
163 to the manufacturer's scanning protocol: light dusting of the
164 teeth surfaces to be scanned (titanium dioxide powder),
165 scanning of prepared tooth, scanning of the remainder of
166 the quadrant, scanning of the opposing quadrant, and finally
167 scanning of the teeth in occlusion as an occlusal registration.
168 After completing the scan sequence, the virtual casts were
169 reviewed in the touch screen attached to the scanning wand,
170 checked for completeness before acceptance, and sent to the
171 certified laboratory paired for the study, for processing of the
172 digital impression, digital die cutting, margin marking, coping
173 design and production.

174 2.4. Crown manufacturing workflow

175 The digitised data from the conventional impression, as well
176 as the captured impressions at intraoral level were transmit-
177 ted to a CAD software program (Lava Design Module, 3M ESPE)
178 in which the copings were designed. Previously, the finish line
179 was marked by the lab technician on the preparation. When
180 the preparation limit was not clear, the technician returned
181 the cast (or the 3D virtual model) to the dentist for the
182 completion of the finish line. This happened only three times.
183 Stereolithographic (SLA) casts for IDI group were produced by
184 rapid prototyping (Fig. 1). The copings for both groups were
185 milled from pre-sintered zirconia blocks (Lava Zirconia Blocks
186 Refill, 3M ESPE). After sintering, copings and SLA casts were
187 sent to the laboratory, where compatible feldspathic porcelain
188 was veneered on the copings on their corresponding cast.

189 2.5. Fit recording

190 Before definitive insertion, silicone replicas were produced for
191 all 60 crowns that were made for the study. To register the
192 space between the inner surface of the copings and the
193 abutment, a modified replica technique was applied^{11,12,22-26}:



Fig. 1 – Stereolithographic cast produced by rapid prototyping.

194 the crowns were filled with a low viscosity silicone (Express 2
195 Ultra-Light Body Quick, 3M ESPE), seated on the preparation
196 and held in place with maximum finger pressure to simulate
197 clinical cementation of the crown. After two and a half
198 minutes (intraoral setting time of the impression material),
199 the crowns were dragged off the preparation with a
200 conventional partial silicone impression (Express 2 Penta
201 Putty as tray and Express 2 Light Body Quick as wash material,
202 3M ESPE).

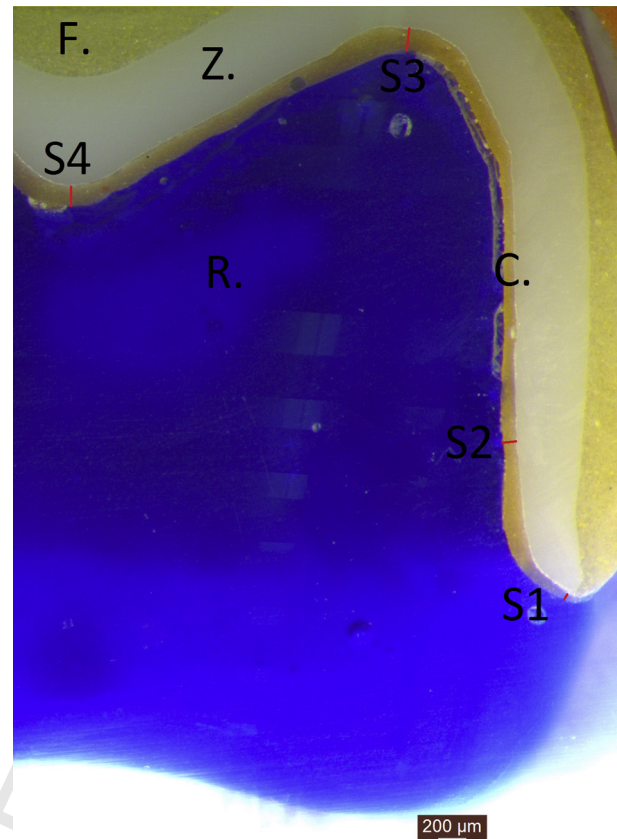
203 Once the replication process was completed with each
204 patient, a third crown, originated from the conventional
205 impression, which still remains the gold standard, was
206 cemented on the prepared abutment by using a luting resin
207 agent (RelyX Unicem, 3M ESPE).

208 As for the two crowns dragged off the tooth, their
209 preparation continued in the lab. To stabilise the thin silicone
210 film representing the cement space, the crowns were embed-
211 ded in an acrylic resin (Pikuplast, Bredent, Senden, Germany)
212 with good dimensional stability properties (lineal contraction
213 $\leq 0.016\%$) that mimicked the abutment tooth. The crowns with
214 the replicated interface, embedded in Pikuplast resin, were
215 further embedded in a transparent resin (Epofix, Struers,
216 Ballerup, Denmark), which facilitated the slicing of the created
217 blocks into 2 mm thick specimens, with parallel walls to
218 obtain a parallel orientation to the microscope plate and to
219 achieve a vertical observation angle, in a bucco-lingual
220 orientation with a precision cutter (Micromet-E, Remet,
221 Bologna, Italy). The sections were polished on a metallurgical
222 polishing wheel by using increasingly fine carbide papers (LS2,
223 Remet). The same operator prepared all samples.

224 2.6. Measurements

225 Film thickness of the replica was captured by means of a
226 stereomicroscope (M-80, Leica, Wetzlar, Germany) at magnifi-
227 cation factor 40 \times , with a built-in charge-coupled camera
228 (Hitachi CCTV HV-720E, Hitachi, Tokyo, Japan). Image analysis
229 software (Leica Application Suite, Leica) was used to measure
230 film thickness at the sites margin, axial, crest, and occlusal
231 fossa (Fig. 2). Marginal gap (S1) was the shortest distance from
232 the restoration to the abutment surface close to the prepara-
233 tion finish line.²⁷ Axial adaptation (S2) was the perpendicular
234 measurement from the internal surface of the coping to the
235 axial wall of the preparation, 2 mm coronal to the
236 cavosurface line angle. Crest discrepancy (S3) was measured
237 from the coping to the abutment at the highest point of the
238 crest, or described as the bisector of the angle between the
239 straight line attached to the incisal plateau and the straight
240 line applied to the axial wall. Finally, occlusal fosse discre-
241 pancy (S4) was measured from the coping to the abutment at
242 the lowest point of the fossa of the preparation.

243 At each site 10 measurements were taken, resulting in 40
244 measurements around each specimen. All measurements were
245 recorded in microns (μm), and exported to a spreadsheet
246 (Microsoft Excel 2007, Microsoft Corp, Redmond, WA, USA). The
247 overall misfit discrepancy was also calculated so as to obtain a
248 complete misfit comparison between both impression meth-
249 ods, conventional and digital intraoral. Two trained investiga-
250 tors, who were previously calibrated and who were not involved
251 in the clinical treatment, carried out the measurement



252 **Fig. 2 – Sample with marked landmarks: (S1–4) margin,**
253 **axial, crest and occlusal fossa gap; (R) acrylic resin**
254 **(replicated abutment); (C) cement space (replicated misfit);**
255 **(Z) zirconia core; and (F) feldspathic porcelain.**

256 procedure of the samples in the stereomicroscope. Finally the
257 average of the two measurements was calculated.

254 2.7. Statistical procedure

255 The sample size utilised was calculated for 80% power by
256 specific software (G-Power version 3.1.9 for Mac OS (Heinrich
257 Heine University, Dusseldorf, Germany). Statistical analysis
258 was performed by software (SPSS 19.0, IBM Corporation,
259 Armonk, NY, USA). Mean values and standard deviations per
260 group were calculated. Normality distribution was checked by
261 using Shapiro–Wilk test. Wilcoxon signed rank test for paired
262 samples was used to assess the influence of the impression
263 system on the internal discrepancy. The level of significance
264 was established at $\alpha = 0.05$.

265 3. Results

266 Of the 34 teeth, one tooth was dropped out of the study
267 because it developed irreversible pulpitis symptoms after
268 preparation, and had to be referred to the Department of
269 Endodontics for root canal treatment. An additional three
270 teeth were dropped out of the study because of damage at
271 sample slicing.

Table 1 – Mean, standard deviations, minimum, maximum values and significance results.

		Mean (microns)	Std. deviation (microns)	(Microns)		Wilcoxon signed rank test
				Min.	Max.	
Margin gap	Conventional	91.46	72.17	6.62	378.30	0.001
	Lava COS	76.33	65.32	6.63	364.45	
Axial gap	Conventional	146.35	66.45	16.98	398.71	0.000
	Lava COS	128.96	62.80	5.72	393.14	
Crest gap	Conventional	200.40	72.42	14.96	393.14	0.403
	Lava COS	195.21	67.44	30.00	394.85	
Occlusal fossa gap	Conventional	224.89	67.52	86.37	391.66	0.008
	Lava COS	198.96	67.81	73.21	398.64	
Overall gap	Conventional	165.77	69.64	6.62	398.71	0.000
	Lava COS	149.86	65.84	5.78	398.64	

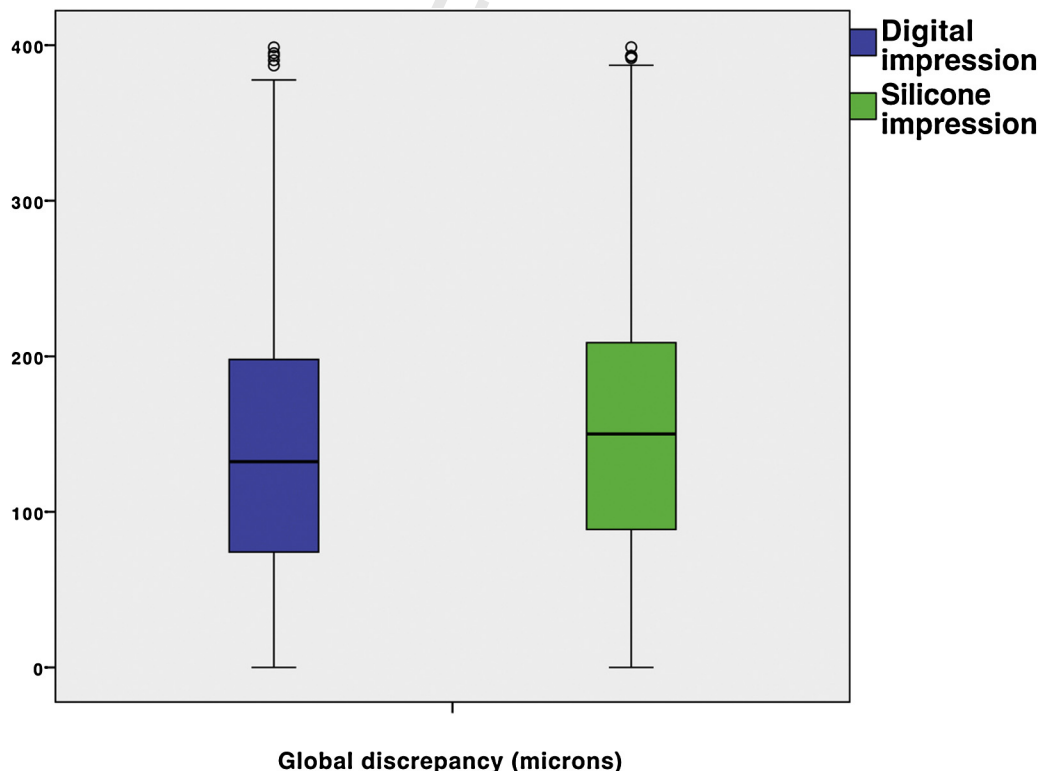
The means, standard deviations and inferior/superior confidence intervals for the internal misfit values (in microns) of the remaining 30 teeth are shown in Table 1. The distribution of the results for both groups can be seen in the boxplot graphs shown in Figs. 3 and 4.

Shapiro-Wilk test detected that the samples did not have a normal distribution, hence the need to perform a non-parametric test. Wilcoxon signed ranked test showed that the IDI restorations had a significantly better fit than the CI group at every site analysed (Table 1) ($p < 0.05$), with the exception of the crest gap. The global comparison also showed significant better fit for the IDI group (Table 1). The lowest misfit was registered at marginal level in both groups, $76.33 \pm 65.32 \mu\text{m}$ for IDI group and $91.46 \pm 72.17 \mu\text{m}$ for CI group. Thus, the null hypothesis was rejected.

4. Discussion

This in vivo study was designed to compare the performance of two different impression systems, a conventional two-step impression technique and a digital intraoral impression technique. CAD-CAM technology has been introduced in the dental field to improve conventional workflows like impression making procedures and design of dental prosthesis. Another purpose of this technology is to allow the fabrication of, between others, high strength ceramic restorations like partially stabilised zirconia frameworks, for which milling is the only approach available nowadays.

There are also many clinical factors, besides impression material and technique, which can influence the quality of an

**Fig. 3 – Box plot general comparison of impression systems.**

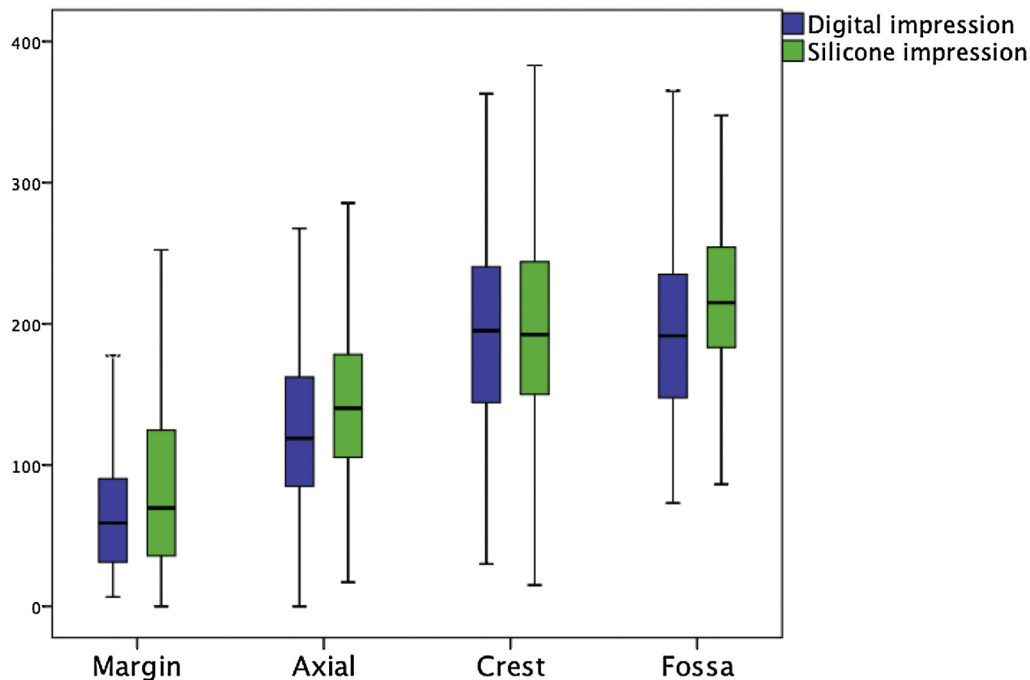


Fig. 4 – Box plot representing comparison of impression systems by site in microns.

impression, including: location of the finish line, periodontal health, sulcus bleeding during impression making, saliva flow rate, or patient compliance. In addition, if the impression is made by means of an intraoral scanner, the accessibility of the preparation for the scanner wand becomes critical for the success of the impression. Accessibility can be limited especially in the retro molar region of patients with limited opening or an ascending ramus of the mandible situated close to the buccal surface of the last molar.¹⁴ For this reason, we decided to analyse the internal and marginal fit with a clinical approach, which had the disadvantage that the evaluation of crown fit was more difficult compared to an in-vitro study where for instance, direct measurement of marginal discrepancies by means of microscopy would have been possible. To overcome this, a replica technique for determining the marginal gap size was adopted. The replica technique is accepted as a reliable and non-invasive means to determine the in vivo adaptation of crown-to-tooth surfaces.^{20,23-26} A modification of the previously described technique in the handling and stabilisation of the replicated silicone layer was used. The misfit replicated space is thin and fragile, with a thickness ranging from 20 to 150 μm . It is a very delicate layer of silicone, to just elevate it from the abutment tooth, embed it in a heavier silicone, and slice it with a blade. This procedure to stabilise the cement space has the benefit of being a simple procedure, but it means also less control over the dimensional stability of the sample, introducing more variables and confounding errors to the results, bearing them less credibility. As described in the material and methods, the cement space replication was dragged out stabilised in the crown and putty/wash partial silicone impression, to proceed with acrylic resin embedding and cutting with a precision cutter.^{6,13}

In the present study, a definition of the marginal accuracy according to Holmes et al.²⁷ was used. The internal gap was defined as the perpendicular distance between the framework and the abutment teeth and it was the misfit of the coping at the axial, crest, and occlusal fossa surfaces. The same measurement at the margin was called the marginal gap. The internal fit is an important factor for the marginal accuracy, since a uniform internal gap width avoids compromising either the retention or the resistance of the restoration and provides an appropriate space to accommodate for the cement.²⁸ On the other hand, the internal fit also has a practical aspect. If too much space is lost as a result of large occlusal discrepancies, the intercuspal clearance available for veneering is reduced.

The data obtained in this study support rejection of the null hypothesis that no differences would be found in fit discrepancy among the crowns fabricated by the two different impression techniques. The mean marginal gap size was 76.33 μm for the digital impression and 91.46 μm for the PVS impression. There are two commonly used impression techniques for PVS: the dual-viscosity one-step impression technique, and the putty-wash two-step impression technique. Several studies have shown that the two-step technique is more accurate than the one-step technique, since it is characterised by uncontrolled wash bulk and a high risk of capturing portions of the prepared margin in the putty material rather than the wash material.²⁹⁻³¹ Therefore, in the present investigation, the putty-wash two-step impression technique was used.

Currently, there are only a few studies available that measured the fit of crowns produced by means of intraoral scanning with a replica technique in vivo. Syrek et al.¹¹ found a

364 median marginal gap size of 49 μm for the digital impression
 365 and 71 μm for the conventional impression; while Scotti
 366 et al.¹² did not have a conventional impression control group,
 367 but on the other hand measured different landmarks of the
 368 preparation: 48.65 μm for the marginal gap, 112.25 μm at
 369 the mid-axial wall, 137.81 μm at the axio-occlusal edge of the
 370 abutments, and 157.25 μm at the centro-occlusal location.
 371 Brawek et al.²⁰ had no control group with a conventional
 372 impression either, as they meant to compare the misfit found
 373 with two different digital intraoral scanners, and their results
 374 were for Lava COS and Cerec AC respectively: at the marginal
 375 gap, 51 μm and 83 μm ; mid-axial, 130 μm and 128 μm ; axio-
 376 occlusal, 178 μm and 230 μm ; and centro-occlusal, 181 μm and
 377 297 μm .

378 The mean marginal gap widths of CAD/CAM-fabricated
 379 zirconia restorations in this study were slightly higher than
 380 the reported literature results at the marginal site. This
 381 could be due to our specimens being finished crowns with
 382 veneered porcelain, whereas Syrek et al.¹¹ and Scotti et al.¹²
 383 only used the copings to measure the fit. Adding porcelain
 384 to copings can cause distortion and lead to an inadequate
 385 fit according to Pak et al.,⁹ whose results of two different
 386 zirconia systems with a presintered milling and totally
 387 sintered milling showed significant differences when analyzing
 388 the marginal gaps before and after porcelain
 389 veneering within each group. However, it remains unclear
 390 whether a difference in mean marginal gap between 40 μm
 391 and 80 μm is a clinically relevant difference. As shown in
 392 Fig. 4, the mean marginal fit of both IDI and CI groups are
 393 within the 100 μm acceptable marginal discrepancy threshold
 394 established for this study. Although the IDI group has a
 395 lower mean, this is not as relevant as the fact that the
 396 3rd quartile of the boxplot graph for the IDI group is below
 397 this threshold, whereas the 3rd quartile on the CI group is
 398 above it.

399 There were some limitations in the present study. The
 400 measurements were performed without cementing the
 401 crowns, so the increase in marginal gap width caused by
 402 cementation was not included. More clinical studies are
 403 needed to establish digital impressions as a gold standard for
 404 impression making in more extensive treatments in fixed
 405 prosthodontics, as well as for implant impressions.

406 5. Conclusions

407 Within the conditions and limitations of this study, the
 408 following conclusions were drawn:

409 The zirconia-based ceramic crowns fabricated using digital
 410 impression obtained better marginal and internal fit than the
 411 crowns fabricated from the conventional impression.

412 The mean marginal discrepancy in both groups was within
 413 the limits of clinical acceptability.

414 Conflict of interest

415 This work has been partially supported by 3M ESPE, but its
 416 contents are solely the responsibility of the authors and do not
 417 necessarily represent the official views of 3M ESPE.

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Appendix A. Supplementary data

Supplementary material related to this article can be found,
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