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Clinical comparison of marginal fit of ceramic inlays between digital and conventional impressions

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PURPOSE. The aim of this stuldy was to compare the clinical marginal fit of CAD-CAM inlays obtained from intraoral digital impression or addition silicone impression techniques. **MATERIALS AND METHODS.** The study included 31 inlays for prosthodontics purposes of 31 patients: 15 based on intraoral digital impressions (DI group); and 16 based on a conventional impression technique (CI group). Inlays included occlusal and a non-occlusal surface. Inlays were milled in ceramic. The inlay-teeth interface was replicated by placing each inlay in its corresponding uncemented clinical preparation and taking interface impressions with silicone material from occlusal and free surfaces. Interface analysis was made using white light confocal microscopy (WLCM) (scanning area: 694 × 510 μm^2) from the impression samples. The gap size and the inlay overextension were measured from the microscopy topographies. For analytical purposes (i.e., 95-%-confidence intervals calculations and *P*-value calculations), the procedure REGRESS in SUDAAN was used to account for clustering (i.e., multiple measurements). For p-value calculation, the log transformation of the dependent variables was used to normalize the distributions. **RESULTS.** Marginal fit values for occlusal and free surfaces were affected by the type of impression. There were no differences between surfaces (occlusal vs. free). Gap obtained for DI group was 164 ± 84 µm and that for CI group was 209 ± 104 µm, and there were statistical differences between them (p = .041). Mean overextension values were 60 ± 59 µm for DI group and 67 ± 73 µm for CI group, and there were no differences between then (p = .553). **CONCLUSION.** Digital impression achieved inlays with higher clinical marginal fit and performed better than the conventional silicone materials. [J Adv Prosthodont 2024;16:57-65]

KEYWORDS
Prosthodontics, Dental inlay, Dental marginal adaptation, Randomized clinical trial

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INTRODUCTION

For many years, the inlays and onlays of several different materials has been regarded by dentists as one of the finest restorations for treating moderate to large carious lesion.[1] They represent a great advantage with longevity and strength as well as aesthetics. To date, prosthetic restorations have been made with a plaster model, which is used in a direct manner to create the prosthesis or is digitally scanned to produce a virtual design.

The application of CAD-CAM technology in dentistry was first proposed by Francois Duret in 1973. In 1989, a more developed system was able to create a dental crown within 4 h. Since then, 3D scanning of dental arches has been used in numerous restoration procedures to create digital impressions for the application of CAD-CAM technology.[2,3] Currently, the most widely used scanners include CEREC Omnicam (Dentsply Sirona, Charlotte, NC, USA), Trios (3Shape, CPH, Denmark), and iTero (Align Technology Inc, Tempe, AZ, USA).

Improvements in digital impression techniques have greatly simplified the process, improving the comfort of patients and the speed of procedures and producing high-quality restorations.[2,4] Also, the benefits of 3D digitization include a reduction in the time required to generate clinical impressions, recently reported to be 23 minutes shorter in comparison to conventional impressions.[5] Intraoral scanners should not only offer good image definition but also allow three-dimensional reproduction. An intraoral scanning may reduce possible distortions caused by conventional impression materials and allow the impression of hollowed-out materials, reducing the amount of material required.

The introduction of CAD-CAM systems has increased the number of inlays used instead of direct restoration techniques and materials; however, further research is required to verify the advantages of these systems.[6,7] Undoubtedly, marginal fit, as a result of marginal gap and overextension control, may lead to plaque accumulation,[8] and this is one of the most important criteria in establishing the long-term functional success of a dental restoration.[9] The main reason of restoration failure is the cement degradation, and the consequent microleakage may result in inflammation of the periodontal tissues and secondary caries in the interface.[10]

Previous studies have used different methods to determine the marginal fit obtained in restorations, and no standardized methodology has been established.[10-19] In addition, these studies have been analyzed *in vitro* and not under clinical conditions. Customarily, *in vitro* measurements are performed using replicas of the definitive crowns and tooth preparations for their analysis. Although there is no consensus on the interface dimension, values of 20 - 200 µm have been reported in the literature.[14,20]

To our knowledge, there is no information about inlay's fit analyzed directly in the mouth of the patient manufactured from a silicone impression or from a digital impression. The null hypothesis of this study was that the clinical marginal fit of inlays fabricated from a silicone impression exhibits similar clinical marginal fit to that of inlays fabricated from a digital impression. The research objective of this clinical study was to compare the clinical marginal fit of CAD-CAM inlays obtained from intraoral digital impression or addition silicone impression techniques.

MATERIALS AND METHODS

The authors declare that they have no conflicts of interest at the time this research project was carried out and at the time that this manuscript was submitted. All procedures performed in this study involving human participant were in accordance with the ethical standard of the Granada University (Spain) (#1456/CEIH/2020) and with the 1964 Helsinki declaration and its later amendments or comparable ethical standard. The clinical trial was registered in the ISRCTN registry (https://www.isrctn.com/ISRCTN84062376) (ISRCTN84062376). Informed consent was obtained from all study participants.

Thirty-one consecutives patients were included in the present study and randomly assigned to an intraoral digital impression (CERECOmnicam, Dentsply Sirona, Charlotte, NC, USA) (group DI) (n = 15) or conventional impression technique (group CI) (n = 16). Randomization was conducted using a mobile application (Randomizer for Clinical Trial, Medsharing, Fontenay-sous-Bois, France) and was based on the order of arrival at the clinic.

The inclusion creteria were:

- Age > 18 yrs.
- In need of 1 - 2 (if located in contra-lateral quadrants and opposing arches) inlays on molar teeth.
- Subject tooth/teeth are free of clinical symptoms.
- No requirement for additional endodontic treatment expressed by the presence of a periapical radiolucency around an endodontically treated tooth or a root canal filling < 3 months.
- Adequate level of oral hygiene expressed by the absence of signs of periodontal inflammation, bleeding on probing, and periodontal pocket depth < 4 mm.
- Capable of signing an informed consent.

The exclusion creteria were:

- Advanced periodontitis affecting the mobility of the teeth (mobility degree 2 or higher).
- Clinical history of bruxism.
- Pregnant or lactating females.
- Marginal preparation situated deeper than 1 mm subgingival.

A total of 31 ceramic inlays were made for the study.

All patients received the same clinical protocol, carried out by the same experienced prosthodontist. The participants received local anaesthesia for the treatment of the abutment teeth that included caries excavation and adhesive built-ups if necessary (Adhesive Scotchbond™ Universal and Filtek Supreme XT, 3M Oral Care, St. Paul, MN, USA). The dental preparations were prepared with diamond burs (Intensiv, D6/6 FG, D34/6C, D6/7FG, FG 50D7/6, Montagnola, Collina d'Oro, Switzerland). The preparation involved at least two walls requiring treatment with the minimum width of 1.5 mm. Evaluation of margins on the occlusal surface and a free surface (vestibular, lingual, or palatal) was done to ensure that the margins did not include occlusion points. The margins were not bevelled and were placed at juxta-gingival level, in any case, not exceeding a subgingival depth of 1 mm.

In both groups, a working model was obtained using an intraoral scanner (CERECOmnicam, Dentsply Sirona, Charlotte, NC, USA). In the DI group, intraoral digital impressions were generated after the clinical preparation by using the Omnicam scanner and CEREC software v. 4.3.1.88305 following the manufacturer's instructions (no additional light, no anti-glare spray, use of a silicone lip retractor to avoid reflections from metal instruments, and previous drying of the area to be scanned). The first step was to fill-in the data on the initial screen, information such as type of restoration, material, abutment teeth or patient's ID. A disposable soft tissue retractor (OptiView; Kavo-Kerr, Charlotte, NC, USA) was placed to retract the cheeks and lips. The mouth was then rinsed with water and air-dried. The scanning started in occlusal direction. Then, the buccal and lingual surfaces were scanned. The quadrant of the prepared tooth, the antagonist arch, and the buccal occlusal bite in maximum intercuspation were scanned. The captured data were checked for artifacts and were used to design the restoration by the lab technician.

In the CI group, a conventional impression was produced by two-step impression technique using addition silicone impression material (Elite HD+ Putty Soft as try and Elite HD+ Light Body as wash material, Zhermack, RO, Badia Polesine, Italy) in a standard metallic tray (Rimlock type, ASA Dental, Bozzano LU, Italy).[21-23] The antagonist arch impression was taken with irreversible hydrocolloid impression material (Hydrogum 5 Zhermack, RO, Badia Polesine, Italy). After removal of the impression, it was examined by a trained observer under 3.3 × magnification (ExamVision HD,Samso, Denmark), and the resulting type III gypsum model (Elite Dental Stone, Zhermack, RO, Badia Polesine, Italy) was scanned at 96 h[24] with the CEREC Omnicam scanner using InLab software v. 4.2.5.82936. Only an experienced operator was involved in digital intraoral scanning and collecting intraoral impressions.

The CAD component of the digital workflow was examined by using CEREC software for the DI group and InLab software for the CI group. The entire restoration process were designed and manufactured under supervision by the same experienced dental technician. The basic steps marked by the computer program were to delimit the finish line, set the cement gap over 50 µm[25] (90 µm), starting 1 mm above the finish line of the prepared teeth, and define the anatomical design of the coping with a minimum thickness of 0.5 mm. Restorations were then milled in feldspathic ceramic (Triluxe, Vita, GmbH & CO. KG, Bad Säckingen, Deuchland) with an MC X milling machine (Dentsply Sirona, Charlotte, NC, USA).

After fitting the definitive restoration to the clinical preparation, with no occlusal check-up,[26] it was placed in the oral cavity and an impression was taken of the occlusal and non-occlusal interfaces using polyvinyl siloxane addition silicone (Elite HD+ Light Body Normal Set, Zhermack, RO, Badia Polesine, Italy) (Fig. 1). Samples were stored in transparent, hermetic bags that were coded to ensure their analysis in a blinded fashion. The same restoration used for the measurements was then cemented in the dental preparation for which it was prepared.

The samples obtained were analyzed by a single observer in a blinded fashion under a white light confocal microscope (WLCM) (PLµSensofar-Tech, Barcelona, Spain) with scanning area of 694 × 510 µm². The concordance of the measurements with those obtained by another expert observer was tested. Each polyvinyl siloxane addition silicone sample, taken directly from the pre-cemented restoration and placed in the dental clinical preparation, was subjected to three readings in three different areas. For each reading, six marginal fit measurements were made: three of the marginal gap and three of the overextension. It was followed by measurement model of Holmes *et al*.[27] Therefore, the term "Marginal gap" was used to refer the perpendicular measurement from the cavo-superficial angle of the tooth to the internal surface of the restoration.[27] On the other hand, the term "overextension" was used to indicate the perpendicular distance from the marginal gap to the restoration margin[27] (Fig. 2). Measurements (in µm) were export-

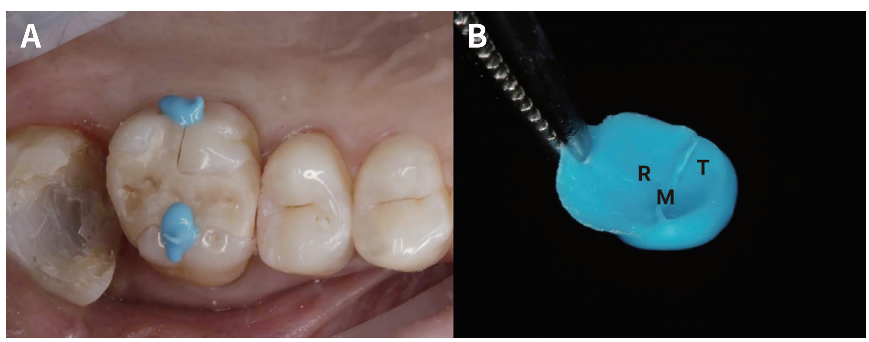

Fig. 1. (A) Clinical restauration with sample. (B) Image of the silicone sample taken directly from corresponding uncemented in the clinical preparation of the patient. M - Replica of the marginal maladjustment; R - Restoration surface; T - Tooth surface.

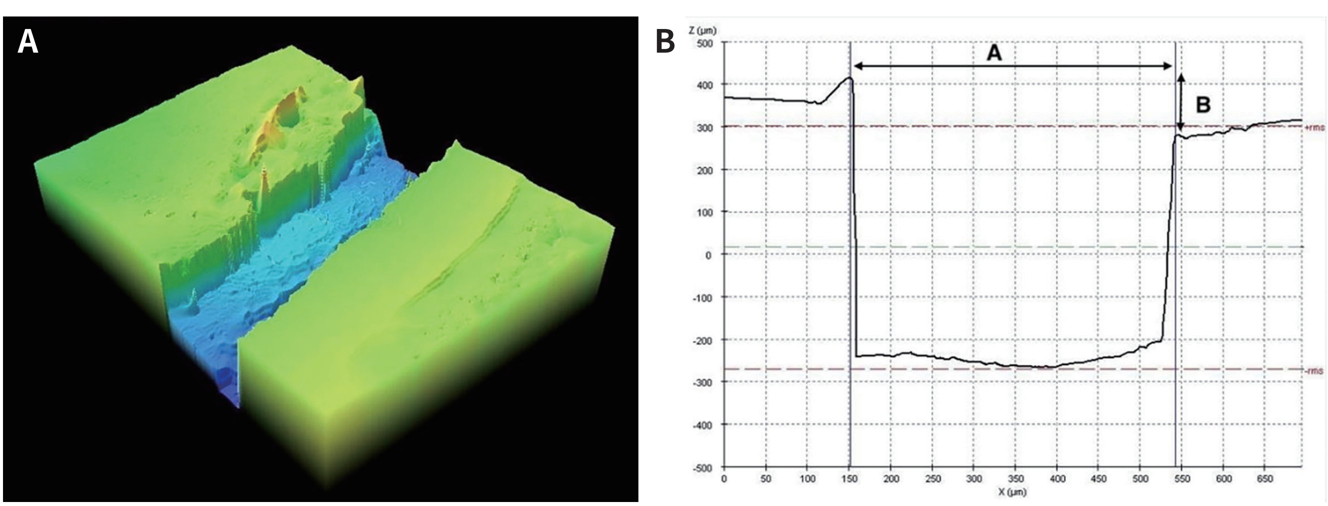

Fig. 2. (A) Image of the 3D reconstruction of the interface seen at the MCLB: M - Replica of the marginal maladjustment; R - Restoration surface; T - Tooth surface. Confocal image of the interface (694 × 510 µm²). (B) Confocal interface profile and measurement. A - marginal gap; B - overextension.

ed to a database.

In this study, the unit of statistical analysis was the measurement (18 measurements were taken per tooth: 9 in occlusal and 9 in non-occlusal). The sample size was initially estimated to achieve an effective n of 26 per group (DI and CI). Assuming a conservative design effect of the mean (Deff) of 10, based on the first cases that were analysed, 260 measurements per group (= 26 × 10) were needed, which would imply 14.4 independent teeth (from independent patients) per group (= 260/18 measurements). Finally, 15 teeth were available in the DI group and 16 in the CI group. This sample size (i.e., 260 clustered measurements per group) allows to compare between the two groups (DI and CI) the quantitative variables of effect (Marginal Gap and Overextension) with a power of 80%, alpha error of 5% and to detect a standardized difference of 0.8 according to Cohen's scale[28] and according to the Sample Power 2.0 software (SPSS Inc., Chicago, IL, USA).

For descriptive purposes (i.e., means and standard deviations), we used IBM SPSS Statistics 22.0 (IBM Corp., Armonk, NY, USA). For analytical purposes (i.e., 95-%-confidence intervals calculations and p-value calculations), we used SUDAAN v.7.0 (RTI, RTP, NC) to account for clustering (i.e., multiple measurements -18- per independent tooth). For *P*-value calculation, we used the log transformation of the dependent variables to normalize the distributions, with the statistical methods expressed in Table footnotes.

RESULTS

Table 1 and Table 2 show the mean values with standard deviations of measurements in the 31 restorations and the differences between groups with the standard error and the 95% confidence interval. The final statistical method is also explained in the each table footnote.

The marginal gap analysis showed that the fit of both occlusal and non-occlusal (vestibular or lingual) surfaces was significantly higher ($P = .041$) in restorations based on intraoral digital impressions than in those based on conventional impressions (Table 1). There were no differences between occlusal and marginal gap in each group. Thus, occlusal and marginal gaps were collapsed to estimate the effect of digital vs. conventional impression (Table 1).

The overextension statistical analysis showed that there were no differences between groups (Table 2). Conventional or digital impression technique obtained the same overextension ($P = .553$). Also, there were no differences between occlusal or free surfaces.

DISCUSSION

The results obtained in this study support the rejection of the null hypothesis that no differences in the marginal fit would be found between the inlays produced from the two different impression techniques.

Other studies obtained values of marginal gap with

Table 1. Marginal gap in µm

Location	Digital Impression (DI)		Conventional Impression (CI)		Difference DI-CI		Comparison
	n[a]	mean ± sd	n[b]	mean ± sd	mean ± se	(95%-CI)	*P*-value[c]
All	270	164 ± 84	288	209 ± 104	-45 ± 24	(92 to < 0)	.041[d]
Occlusal	135	184 ± 98	144	228 ± 107	-44 ± 31	(104 to 16)	.087[d]
Non-occlusal	135	144 ± 61	144	190 ± 97	-46 ± 25	(95 to 3)	.082[d]

sd: standard deviation; se: standard error corrected for clustering (i.e. multiple measurements per each single independent tooth): 95%-CI: confidence interval corrected for clustering.

a: Based in 15 independent teeth (i.e., coming from different patients). For each single tooth there are 9 measurements in occlusal locations and 9 measurements in non-occlusal locations.

b: Based in 16 independent teeth (i.e., coming from different patients). For each single tooth there are 9 measurements in occlusal locations and 9 measurements in non-occlusal locations.

c: Statistical tests are made with logX, where log is decimal logarithm and X is the marginal GAP. The interaction Digital/Conventional impression x Location was non-significant ($P = .996$), by using procedure REGRESS in SUDAAN to account for clustering (i.e., multiple measurement per each single independent tooth). Thus, we can collapse Occlusal and Non-occlusal locations to estimate the effect of Digital/Convention impression.

d: Procedure DESCRIPT in SUDDAN.

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Table 2. Overextension in μm

Location	Digital Impression (DI)		Conventional Impression (CI)		Difference DI-CI		Comparison
	n[a]	mean ± sd	n[b]	mean ± sd	mean ± se	(95%-CI)	*P*-value[c]
All	270	60 ± 59	288	67 ± 73	-8 ± 12	(-32 to 16)	.553[d]
Occlusal	135	52 ± 45	144	69 ± 57	-17 ± 12	(-40 to 7)	.233[d]
Non-occlusal	135	67 ± 70	144	66 ± 86	1 ± 18	(-34 to 36)	.940[d]

sd: standard deviation; se: standard error corrected for clustering (i.e. multiple measurements per each single independent tooth): 95%-CI: confidence interval corrected for clustering.
a: Based in 15 independent teeth (i.e., coming from different patients). For each single tooth there are 9 measurements in occlusal locations and 9 measurements in non-occlusal locations.
b: Based in 16 independent teeth (i.e., coming from different patients). For each single tooth there are 9 measurements in occlusal locations and 9 measurements in non-occlusal locations.
c: Statistical tests are made with logX, where log is decimal logarithm and X is the marginal GAP. The interaction Digital/Conventional impression x Location was non-significant (*P* = .272), by using procedure REGRESS in SUDAAN to account for clustering (i.e., multiple measurement per each single independent tooth). Thus, We can collapse Occlusal and Non-occlusal locations to estimate the effect of Digital/Convention impression.
d: Procedure DESCRIPT in SUDDAN.

a great discrepancy. Values were found between 35.4 and 246 μm.[8,14,20,29] At present, no consensus has been reached for a marginal discrepancy value that is clinically acceptable,[30] but a recent study reported that overall mean values of the marginal fit remained under the 120 μm.[8,31] The reason of this great discrepancy could be based on the different methods in each study. Several studies have evaluated the margin *in vitro*[16-18,20,29,32-45] using different techniques as: scanning electron microscope, computed X-ray microtomography (micro-XCT), and triple scan protocol as previously described by Holst and colleagues.[46,47] It is therefore difficult to directly compare the results among different studies. In addition, most of these studies used all-ceramic crown restorations; inlays have more complex geometry than crowns.[8] This parameter is fundamental in explaining the difference found between our study results and other studies results. However, all studies seem to indicate predictable marginal adaptation with or close to the thresholds of clinical acceptability.

To the best of our knowledge, no study has compared marginal adaptation previously by directly taking the clinical marginal gap samples in the patient. This method is simple and economic and allows a direct evaluation of the actual situation in the oral cavity after setting CAD-CAM restorations and a higher clinical reproducibility.

The definition of misfit varies among investigators and has not been described strictly. Studies have measured fit as marginal adaptation, internal adaptation, vertical seating, radiographic appearance, and clinical adaptability, which has caused confusion, particularly when comparing the results of different studies.[8] Consequently, in this study, we used the terms as described by Holmes and colleagues.[27] This method accounts for both overextension and marginal gap of dental restoration, thus providing very accurate descriptions of marginal accuracy.

Lower marginal gap values were recorded in the preparations based on digital impressions in comparison to those fabricated from conventional impressions. This is translated to a higher marginal fit. There are multiple factors that explain this result. (e.g., materials and impression technique) The factors reported to affect the quality of impressions are: localization of the finish line; periodontal health; sulcus bleeding during the impression; salivary flow; patient collaboration, especially in the retromolar area (e.g., ascending mandibular ramus); mouth opening capacity of patients; and interposition of the tongue.[10-12] Other factors influencing the fit of inlays obtained with CAD-CAM systems include: the ability and experience of the CAD-CAM system operator, the intrinsic limitations of the device, and the sculpted unit, software, and design algorithms used. The results could be affected by the used materials such as: different types of stock trays, and silicone and gypsum which may cause dimensional changes in the resulting model.[24,48]

When examining overextension, which is the least favourable parameter since it can lead to plaque accumulation, we obtained a large dispersion of data. This could be explained by the orientation of the free walls of the preparations and the influence of the mobile mucosa and tongue on the resulting digital model.[10-12] It is interesting to find only 1 study in the literature measured overextension for restorations with inlays. Also, it is interesting to note that in Alajaji's study,[33] which also had overextension as a study objective, they obtained similar data with our results.

Further clinical studies are required to establish digital impression as a "gold standard" for the manufacture of fixed prostheses. From the data of this study, digital impressions achieve improved outcomes in comparison to conventional impressions and facilitate the digital workflow.

CONCLUSION

Within the limitations of the present study, we can conclude that digital impression achieves inlays and onlays with better clinical marginal fit and could replace conventional silicone materials. Besides, the study suggests that digital impressions improve clinical outcomes and facilitate digital workflow.

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