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CAD-CAM and analog occlusal splints comparison based on the amount of occlusal adjustments. 3D analysis of the volumetric changes: A pilot study

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Abstract

Objective: To evaluate the volumetric changes on occlusal surface of computer-aided design and computer-aided manufacturing (CAD-CAM) occlusal devices fabricated following a fully digital workflow after occlusal adjustment, compared to those fabricated with an analog workflow.

Materials and Methods: Eight participants were included in this clinical pilot study, receiving two different occlusal devices fabricated with two different workflows, fully analog and fully digital. Every occlusal device was scanned before and after the occlusal adjustments to compare the volumetric changes using a reverse engineering software program. Moreover, three independent evaluators assessed a semi-quantitative and qualitative comparison using visual analog scale and dichotomous evaluation. The Shapiro–Wilk test was performed to validate normal distribution assumption, and a dependent t-Student test for paired variables was used to determine statistically significant differences (p-value < 0.05).

Results: The root mean square value was extracted from the 3-Dimensional (3D) analysis of the occlusal devices. The average values of the root mean square were higher for the analogic technique (0.23 ± 0.10 mm) than the digital technique (0.14 ± 0.07 mm) but the differences were not statistically significant (paired t-Student test; $p = 0.106$) between the two fabrication techniques. The semiquantitative visual analog scale values between the impression for the digital (5.08 ± 2.4 cm) and analog (3.80 ± 3.3 cm) technique were significant ($p < 0.001$), and statistically significant differences values were assessed for evaluator 3 compared to the other evaluators ($p < 0.05$). However, the three evaluators agreed on the qualitative dichotomous evaluation in 62% of the cases, and at least two evaluators agreed in 100% of the evaluations.

Conclusions: Occlusal devices fabricated following a fully digital workflow resulted in fewer occlusal adjustments, as they could be a valid alternative to those fabricated following an analog workflow.

Clinical Significance: Fabricated occlusal devices following a fully digital workflow could have some advantages over analog workflow such reduce occlusal adjustments at delivery appointment, which can result in reduced chair time and therefore increased comfort for the patient and clinician.

KEYWORDS
analog, digital, milled, occlusal device, occlusion, precision

1 | INTRODUCTION

Temporomandibular disorders (TMD), and bruxism are common conditions with high prevalence rates reported in clinical practice.[1,2] For the vast majority of clinicians an occlusal device (OD) is the first evidence-based treatment of choice for these conditions.[3–7]

Over recent years, the use of intraoral Scanners (IOSs) have become more widespread in all dental disciplines.[8–10] Nowadays, the level of accuracy of intraoral digital scans from different IOSs are reliable, and provide clinically acceptable outcomes on single-unit, and short-span fixed dental prostheses on teeth and implants.[10–12]

Nevertheless, the accuracy of IOSs for complete-arch intraoral digital scanning remains inferior compared to analog impression methods. More supporting literature is needed to recommend the systematic use of IOSs for complete-arch intraoral digital scans.[13,14] Furthermore, it is well known that occlusion is one of the cornerstones for the long-term success of any prosthodontic treatment.[15–18]

Several clinical studies have proven the successful production of occlusal devices following different digital approaches, and without the need for a physical cast, or articulator mounting. The previous published clinical research was focused mainly on the description of the technique.[19,20] Others conclude that high-quality Michigan splints can be fabricated by using a fully digital workflow.[21] While other authors evaluated the patient's preferences in a random crossover study.[22]

To the best of the authors' knowledge, studies quantitative evaluating the extent of occlusal modifications of analog or digitally fabricated ODs after intraoral occlusal adjustment are lacking. For this reason, this clinical pilot study aims to evaluate the volumetric changes on occlusal surface of computer-aided design and computer-aided manufacturing (CAD-CAM) ODs fabricated following a fully digital workflow before and after occlusal adjustment, compared to those fabricated with an analog workflow.

The research hypothesis was that ODs fabricated following a fully digital workflow had the same amount of occlusal adjustment as those fabricated following an analog workflow.

The secondary hypothesis was that there were not significant discrepancies between different workflows utilizing semi-quantitative assessment methods.

2 | MATERIALS AND METHODS

2.1 | Study design & patient selection

The present study was approved by the Comité Ético de Investigación Clínica/Committee for Ethics in Clinical Research (CEIC) of the Universitat Internacional de Catalunya (REST-ECL-2021-07) and registered at ClinicalTrials.gov (NCT05317182), carried out in accordance with the Declaration of Helsinki, the ISO EN 14155. Eight participants were recruited using the following inclusion criteria: patients had to be 18 years or older, medically healthy without alcohol or drug addiction, fully dentate with presence of first molar in both arches, bruxism or dental wear facets, and agreement to participate in the study. To participate, all the patients were required to sign an individual informed consent form. Eight participants were included in this clinical pilot study.

In this study, each patient received two ODs manufactured using two different methods: Digital and Analog method. The Analog workflow consisting of a silicone impression, silicone interocclusal registration and analog fabrication is termed Group 1, while Group 2, the Digital workflow, consists of a digital impression, digital interocclusal registration and digital design and milled fabrication. The study was divided into three sessions, two clinical sessions and one laboratory session.

2.2 | Data acquisition

All clinical procedures were done by the same operator, prosthodontist with 5 years' experience. At the first clinical session, the different impression types and the maxillomandibular relationship were recorded. During the impression taking all participants were in a supine position, wearing a lip retractor (Optra-Gate; Ivoclar Vivadent; Schaan, Liechtenstein), and the impression areas were dried. The maxillomandibular relationship was recorded in centric relation (CR) with the help of an anterior deprogramming device type Lucia's jig placed for 5 min[23–25] in mouth made with light cured resin (Techim Revor Light; Techim Group s.r.l.). Once the patient was in CR, this condylar position was fixed by adding light cure resin (Triad Gel; Dentsply Sirona) on the buccal surface of the mandibular incisors. This maxillomandibular relationship was recorded with a quick-setting addition polyvinyl siloxane impression material (Futar D Regular; Kettenbach,

Eschenburg, Germany). The different samples of the centric relation records were measured with a caliper (Calipretto CR; Renfert, Hilzingen, Germany) to ensure a minimal thickness of 1.5 mm at the level of the first molars.

For Group 1, definitive impressions of the mandibular and the maxillary arches were taken with polyether impression material (Impregum Penta Soft; 3 M ESPE, Neuss, Germany) mechanically mixed (Pentamix Soft; 3 M ESPE, Neuss, Germany) with metallic non-perforated stock trays. A facebow record (Artex Facebow; Amann Girrbach, Germany) was taken with a quick-setting addition polyvinyl siloxane impression material (Futar D Regular; Kettenbach, Eschenburg, Germany).

For Group 2, complete arch intraoral digital scans of the maxillary and mandibular arches were performed (Trios; 3Shape Dental Systems, Copenhagen, Denmark) (Base type Pod) (Unit version 1.7.33.1) following the scanning protocol recommended by the manufacturer. The IOS was first calibrated before its use with every patient; then, the scans were acquired taking into account the optimal conditions for scanning.[26–28] To obtain a digital scan of the CR, the anterior deprogramming device, and polyvinyl siloxane CR records, used previously for the analog workflow, were placed again in mouth by parts (anterior deprogramming device and polyvinyl siloxane CR records of the opposite side). Intraoral CR digital scans were made covering from distal canine to mesial of second molar, each side.[29,30]

Despite the different fabrication methods, to make the ODs comparable some standardized fabrication guidelines were established. The common guidelines were: devices were located on the maxillary dentition, all maxillary teeth were covered, minimum 1.5 mm interocclusal thickness between the posteriors (first molars), 1 mm of buccal extension below from the survey line flat, smooth occlusal contact, surfaces balanced, simultaneous static occlusion between the occlusal device and all the buccal cusps of the mandibular teeth, posterior disocclusion during lateral and protrusive movements, condylar inclination of 25°, immediate side shift of 2 mm, progressive side shift of 10° were selected as standard parameters.[17,18,22]

The silicone impressions were poured 30 min after acquisition with dental stone type IV (Fugi Rock; GC Europe, Leuven, Belgium) following the manufacturer's proportions and recommendations (standard water/powder ratio: 20 mL/100 mg). After setting, the models were removed from the impressions and trimmed. The casts were then mounted on a semi adjustable articulator (Artex CR; Amann Girrbach, Germany) with dental plaster of Paris (Snow White Plaster No.2; Kerr, California, USA) using the previous records.

The analog ODs were fabricated from a previously designed wax prototype (Pink wax; Cera Reus, Tarragona, Spain), which was embedded with polyvinyl siloxane impression material (Zetalabor; Zhermack, Germany). After wax removal, the impression was poured with self-curing acrylic resin (Paladur, Clear; Kulzer Hessen, Germany). Finally, the ODs were manually adjusted in static occlusion on the articulator with 40 μ blue articulating paper (Arti-Check micro-thin 40 μ, blue; Dr. Jean Bausch, Cologne, Germany).

The digital scans were imported into a CAD software program (3Shape Ortho Analyzer; 3Shape, Copenhagen, Denmark) for the design process. The selected virtual articulator and their semi adjustable parameters were the same as for the conventional workflow. The value for the contact point between the flat surface of the OD and the buccal cusps of the mandibular teeth was 40 μ. However, manual modifications with the virtual wax knife were often needed to achieve the predefined common guidelines.

For the CAM process clear blanks of Polymethyl Methacrylate (PMMA) (Zirlux Splint Transparent; Henry Schein, USA) were milled with a five simultaneously operating axes milling machine (vhf camfacture; Ammerbuch, Germany). After milling, the ODs were removed with a handpiece from the rest of the blank and manual smoothing and polishing was performed.

At the second clinical session, the fit and the retention of both ODs were checked intraorally and adjusted as needed. To make the standard tessellation language (STL) files more uniform, a preadjustment of the intraoral digital scan of the maxillary arch with the OD inserted was performed. Contrary to the initial records, in this case the palate was not captured. The scanning conditions were the same as mentioned for the first intraoral digital clinical session, however for the scanning strategy, the vestibular part was scanned first, to have references for the scanner not getting lost. This process was done first with the conventional OD and immediately after with the digital OD. These initial intraoral scans were exported as STL files and named depending on the participant's data, for example, STL conventional device-participant 1-preadjustment ($STL_{C\text{-}1\text{-}PRE}$) or STL digital device-participant 1-preadjustment ($STL_{D\text{-}1\text{-}PRE}$).

The static and dynamic occlusion was checked with 40 μ blue and red articulating paper respectively (Arti-Check micro-thin 40 μ,

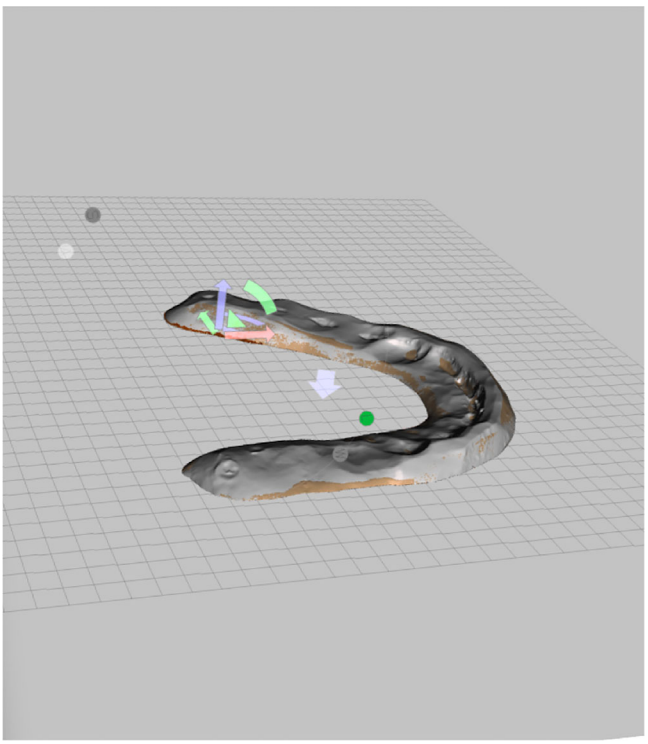

FIGURE 1 Trimmed STL below the equator line using "plane cut" tool.

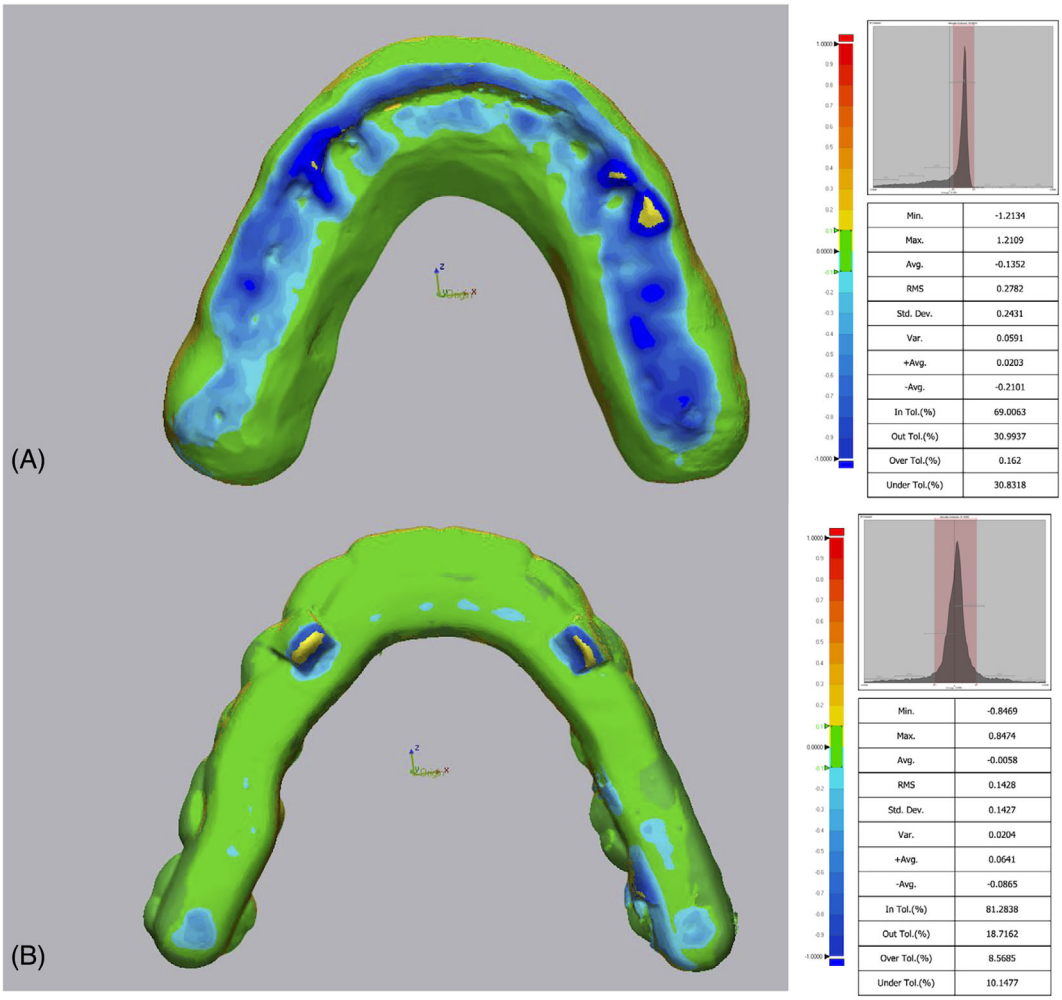

FIGURE 2 3D analysis and report. (A) Root Mean Square (RMS) color-difference map and values of analogic technique. (B) RMS color-difference map and values of digital technique.

blue/red; Dr. Jean Bausch, Cologne, Germany) and if required the ODs were manually adjusted with the handpiece. Subsequently, post-adjustment intraoral digital scans were performed. These new intraoral digital scans were also exported and named following the same guidelines, for example, STL conventional device-participant 1-postadjustment ($STL_{C\text{-}1\text{-}POST}$) or STL digital device-participant 1-postadjustment ($STL_{D\text{-}1\text{-}POST}$).

To eliminate potential errors during the mesh comparison, before the 3-Dimensional (3D) analysis the STLS were trimmed with the "plane cut" tool below the equator line using an open-source software (Meshmixer 3.5; Autodesk), leaving the entire occlusal area and part of the vestibular and lingual areas to be evaluated (Figure 1).

2.3 | Quantitative analysis

After the occlusal adjustment the different files were superimposed individually with its respective pre-op scan ([$STL_{C\text{-}1\text{-}PRE}$ – $STL_{C\text{-}1\text{-}POST}$] and [$STL_{D\text{-}1\text{-}PRE}$ – $STL_{D\text{-}1\text{-}POST}$]) through a best-fit algorithm of the entire dataset for closest-point matching of both surfaces in a reverse engineering software program (Geomagic Control XTM; Geomagic, 3D Systems, USA). Utilizing this software, the Root Mean Square (RMS) estimate resulting from the color-difference map was used to indicate how far the deviations between the compared datasets were from zero. The evaluation of distances between specific points, globally and in x, y, and z planes is allowed by the color-difference maps. The lower the RMS obtained, the higher the degree of 3D matching of the superimposed data.[31–33]

After the occlusal adjustment the different STL files were superimposed individually with its respective pre-adjusted scan ($STL_{C\text{-}1\text{-}PRE}$ – $STL_{C\text{-}1\text{-}POST}$ and $STL_{D\text{-}1\text{-}PRE}$ – $STL_{D\text{-}1\text{-}POST}$) through a best-fit algorithm for closest-point matching of both surfaces in a reverse engineering software program (Geomagic Control X; 3D System Inc). Again, the Root Mean Square (RMS) estimate resulting from the color-difference map was used to indicate how far the deviations were from zero between these datasets. The evaluation of distances between specific points, globally and in x-, y-, and z- planes is allowed by the color-difference maps. Low RMS obtained means high trueness, result of higher degree 3D matching of the superimposed data[31,32] (Figure 2).

Moreover, a color-coded deviation map with maximum/ minimum deviation values were also set at +100/100 μm with a tolerance range of +10/10 μm to display the distances between both files. RMS error measurement positive discrepancy (cool colors) denoted that the reference STL file, which corresponds to the pre-adjustment intraoral digital scan, was bigger than the experimental STL file, corresponding to the post-adjustment intraoral digital scan. This procedure was done for all the ODs of all the participants.

2.4 | Semi-quantitative and qualitative evaluation

Standardized questionnaires show values for specified parameters from the perspective of the operators. Visual Analog Scale (VAS) of 10-centimeter, that enabled a semi-quantitative assessment, was used where the independent evaluators marked a line in a location they would appreciate as the best fit for the comparison in terms of more or less discrepancy. The data acquired from the different VASs were measured with a digital caliper (digital caliper 0–150 mm; Horex, Germany), followed by the measurement of the line and assignment of a numeric value. Moreover, a qualitative Dichotomous Evaluation (DE) was performed on a model sheet. The evaluators observed two images, one from the analog OD and the other from the digital. Based on the color code that the 3D report displayed, the evaluators selected the image which appeared to have the least discrepancy. This assessment served as a mean of calibration between the evaluators.

2.5 | Statistical analysis

Average and standard deviation values were determined as descriptive statistics for RMS and VAS. The Shapiro–Wilk test was performed to validate normal distribution assumption of sample data for both VAS and RMS. Consequently, parametric statistics were used for further analysis. Variance homogeneity of different groups for both RMS and VAS values was assessed using the Levene's test. A dependent t-Student test for paired variables was used to determine statistically significant differences in RMS for ODs fabricated with the traditional/ analogic (Group 1-A) and digital (Group-D) method (p-value < 0.05). A two-way ANOVA table with operator (operator 1, operator 2, operator 3) and fabrication method (analogic, digital) factors with HSD Tuckey post-hoc multiple comparison test was used to assess significant differences for VAS values (p-value < 0.05).

3 | RESULTS

All the patients received 2 occlusal splints from each technique (Digital and Analogic). No patients were lost in the study. RMS value was extracted from the 3D analysis of 16 ODs (Group 1 = 8 and Group 2 = 8). Table 1 summarizes the results each 3D report. The average values of RMS were higher for the analogic technique (0.23 ± 0.10 mm) than the digital technique (0.14 ± 0.07 mm) but the differences were not statistically significant (paired t-Student test; $p = 0.106$) between the two fabrication techniques (Table 1, Figure 3).

TABLE 1 RMS values for each sample (mm).

RMS values of each OD's		
Sample	**Type of sample**	**RMS value**
1	A	0.28
2	D	0.14
3	A	0.16
4	D	0.14
5	A	0.37
6	D	0.20
7	A	0.18
8	D	0.10
9	A	0.39
10	D	0.07
11	A	0.17
12	D	0.05
13	A	0.09
14	D	0.25
15	A	0.20
16	D	0.17

Abbreviations: A, analogic; D, digital; RMS value, Root Mean Square value.

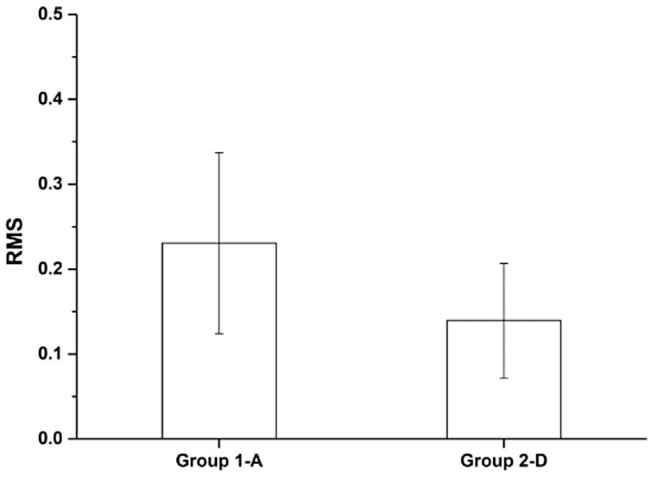

FIGURE 3 Root Mean Square values for two methods of OD fabrication tested.

The semi-quantitative analysis, in which the evaluators have a notable role in the assessment value; differences in VAS values between the impression for the digital (5.08 ± 2.4 cm) and analog (3.80 ± 3.3 cm) technique were significant (p < 0.001) (Figure 4A). Moreover, statistically significant differences in the VAS values (p < 0.05) were assessed for evaluator 3 compared to both evaluator 1 and evaluator 2, which was not associated with the method of fabrication of the ODs (Figure 4B).

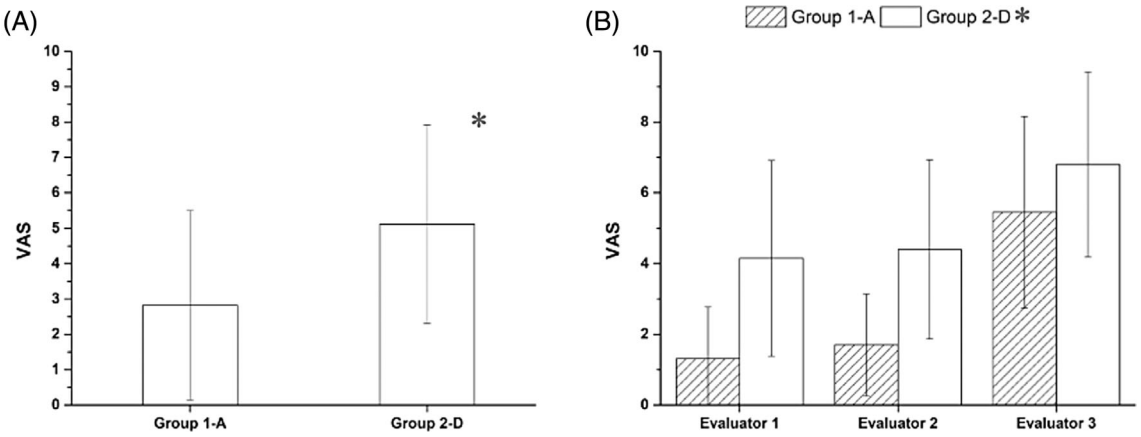

FIGURE 4 (A), VAS values for two methods of OD fabrication tested. (B) VAS values for each evaluator. *Denotes statistically significant differences between groups ($p < 0.05$).

The three evaluators agreed on the qualitative dichotomous evaluation in 62% of the cases and at least two evaluators agreed on the DE in 100% of the evaluations.

4 | DISCUSSION

This research evaluated the discrepancies at the occlusal surface found between analog and digital workflows when processing a maxillary occlusal appliance. Two devices were fabricated for each patient, one using polyether impression materials, and the other with a fully digital workflow. The amount of adjustment needed during the delivery appointment was measured for each device. A quantitative analysis through RMS was done for every appliance before and after intraoral adjustments to indicate the accuracy. Moreover, a semiquantitative and qualitative evaluation was performed with VAS and DE by 3 calibrated evaluators. The present study showed a higher amount of occlusal adjustments in the analog method when compared to digital workflow with no statistical difference when determining a quantitative measurement such as RMS. Therefore, the research hypothesis that ODs manufactured following a fully digital workflow would be equivalent in terms of occlusal adjustments to those fabricated following a conventional workflow was accepted. The semiquantitative assessment of the same discrepancy measured with the VAS values was statistically significant for the analog and digital techniques, consequently the secondary hypothesis was rejected.

The visual differences between both splints did not allow to be a double-blind study, however, the research structure with only one clinician reduced the chances of possible differences between operators. Even though it was not a randomized clinical trial, giving two splints to each patient allowed the comparison between both systems. Specifically, the difference in occlusal registration at increased Vertical Dimension of Occlusion (VDO) using silicone and IOS.

There are several studies evaluating the analog impression and IOS, however, they are mainly in vitro studies.[34–36] Therefore, studies comparing these two methods on an in vivo environment are limited; especially presenting and evaluating a quantitative property, such as RMS, that represents the amount of chair side adjustments needed at prostheses delivery for both methods.[14] Furthermore, the participation of three calibrated evaluators enabled collection of relevant data to compare both systems and the potential individual bias.[36,37]

Maxillary and mandibular impressions were done using polyether material and poured in type 4 dental stone. Interocclusal relationship was registered using polyvinyl siloxane material.[38] At the same time, IOS was used to digitally register maxillary and mandibular arches and interocclusal relationship at increased vertical dimension of occlusion. Protocol of a recent publication was followed; however, in their research the inter-arch relationship was taken at maximum intercuspation.[25] This may have created an interocclusal relation discrepancy due to the need of a VDO increase in the laboratory prior to device fabrication. Potential occlusal errors that could lead to increased adjustment at delivery date were avoided by registering the increased VDO intraorally. A qualitative study published found a greater amount of time required for adjustment in analog splints using Wilcoxon-Mann–Whitney-U-Test, but results showed no statistical significance.[25] In another study, a Koch crossover test showed IOS to be more comfortable than a silicone impression.[39] Furthermore, other authors analyzed impression techniques in a randomized controlled trial. Their findings expressed patient-reported outcome measures (PROMs) with VAS higher patient satisfaction while using IOS compared to silicone impressions.[40] In our study, neither time not patient's satisfaction was evaluated; however, all those finding are relevant towards using IOS rather than silicone impressions.

As mentioned, although adjustment time and comfort were not measured in this study, amount of adjustment was measured with RMS and found that adjustment in digital devices was comparable to analog devices.[40] Interestingly, the semiquantitative comparative assessment of the same adjustment between digital and analog ODs measured with the VAS values was significantly different ($p < 0.01$). This significance might be related to higher discrepancies in assessment when evaluators judge the adjustment of the ODs. These discrepancies between evaluators were validated as VAS values

determined by evaluator 3 compared to the other two evaluators were significantly higher. Thus, visual inspection of the OD adjustment by evaluators might not be a reliable assessment to compare and assess the two methods investigated here. The evaluators should undergo a more extensive training process for reducing bias in VAS assessment. When dichotomous assessment was performed, higher agreement was found between evaluators. This finding may be due to the higher simplicity of the dichotomous assessment, when compared to the VAS values, for determining the highest discrepancy in adjustment between the two OD methods.

A study analyzed the accuracy of three different digital methods compared to articulating paper as analog method.[41] The receiver operating characteristic curve results for the intraoral scanner showed an area under the curve (AUC) of 0.817, indicating the best out of the three groups on discrimination power to detect occlusal contacts. Their dichotomy variable by two calibrated examiners to evaluate the three systems was analyzed using Pearson's chi-squared test and Cohen's kappa coefficient showing statistically greater reliability using IOS than analog methods. Other authors concluded similarly as they assessed higher accuracy in virtual occlusion procedures than analog records.[17] Data in this study showed concordance with the described data resulting in less need of occlusal adjustment using IOS than silicone impression.

Two types of splints evaluated in this study had totally different fabrication processes, one self-curing acrylic resin, and the other one is CAD-CAM milled Polymethyl Methacrylate. The fabrication process and the material difference could have had an influence on the discrepancies found in this study. Mechanical properties of these two types of materials were compared finding no statistically significant differences; however, the fabrication process accuracy was not evaluated.[42]

The limitations in this clinical research were the impossibility of being double blinded due to easy identification of both splints, the small sample size, and consequently not being a randomized clinical trial. Future studies could evaluate the laboratory perception of difficulty in fabrication as well as time and compare patient comfort between the hand made and the CAD-CAM fabricated occlusal devices.

5 | CONCLUSIONS

Based on the findings and within the limitations of this clinical pilot study, the following conclusions were drawn:

1. Occlusal devices fabricated following a fully digital workflow are similar in terms of occlusal adjustments when 3D volumetric evaluation is performed, to those fabricated following an analog workflow.
2. The semiquantitative assessment of the same discrepancy measured with Visual Analog Scale values was statistically significant for digital method compared to analog OD.

AUTHOR CONTRIBUTIONS

Alvaro Blasi: Investigation, Methodology, Supervision, Conceptualization, Writing – original draft, Writing – review & editing. **Víctor Henarejos-Domingo:** Supervision, Conceptualization, Writing – original draft, Writing – review & editing. **Ricardo Palacios-Bañuelos:** Investigation, Methodology, Software, Supervision, Conceptualization, Writing – original draft, Writing – review & editing. **Carla Vidal-Ponsoda:** Digital protocol and data analysis. **Conrado Aparicio:** Software, Methodology, Supervision, Data curation, Validation, Writing – review & editing. **Miguel Roig:** Supervision, Conceptualization, Validation, Writing – review & editing.

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CONFLICT OF INTEREST STATEMENT

The authors declare that they do not have any financial interest in the companies whose materials are included in this article.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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