THE JOURNAL OF PROSTHETIC DENTISTRY

CLINICAL RESEARCH

Fit of complete-arch implant-supported prostheses produced from an intraoral scan by using an auxiliary device and from an elastomeric impression: A pilot clinical trial

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ABSTRACT

Statement of problem. The accuracy of impressions for implant-supported prostheses is essential to ensure a passive fit of the definitive prosthesis. Intraoral scanners (IOSs) have been developed as an alternative to complete-arch implant-supported restorations; however, whether they are sufficiently accurate when more than 3 nonaligned implants are involved is unclear.

Purpose. The purpose of this pilot clinical study was to determine whether the fit of complete-arch zirconia implant-supported frameworks processed on a cast obtained with an IOS and adjusted with an auxiliary device is equivalent to a prosthesis obtained from an elastomeric impression.

Material and methods. Twelve consecutive participants who were ready for complete-arch restorations on already osseointegrated implants were enrolled. Two records were made, one open-tray with polyether and splinted impression copings and the second with an IOS. A verification gypsum device was used for the elastomeric impression, and a prefabricated auxiliary device was used to adjust the intraoral scans. Two zirconia frameworks with the same design were processed and evaluated intraorally by 2 independent calibrated observers.

Results. In 11 of the 12 participants, the digitally processed prosthesis was preferred over the conventionally processed prosthesis. The clinical fit of the prostheses obtained with the completely digital workflow was better than that of those obtained with the conventional workflow.

Conclusions. The use of a prefabricated auxiliary device after intraoral scanning allowed delivery of complete-arch implant-supported monolithic zirconia prostheses with a fit better than those fabricated from conventional impressions. (J Prosthet Dent 2021;■:■-■)

An accurate impression is essential to ensure an implant-supported prosthesis with a passive fit.[1] Without a passive fit, the components around the implant prosthetic framework are prone to biological and mechanical problems.[2-5] Even slight discrepancies can produce stress and strain on the framework and the implants,[4] with different effects depending on framework material.[6] The use of rigid frameworks such as those made from zirconia might magnify those effects.[7] Unlike tooth-supported restorations, where up to 100 µm of tooth movement can help absorb a certain amount of misfit, implant movements are limited to 10 µm.[8] Nevertheless, even in such situations, there remains a biologic tolerance to misfit.[9]

Since an absolute passive fit is not achievable,[10] some authors[4,11-15] have proposed an acceptable misfit range from 30 µm to 100 µm, although a quantifiable misfit without adverse effects is difficult to determine.[16,17] Although according to the recommended standard of practice, clinicians try to provide prostheses that exhibit passive fit,[5,18] evidence of the impact of marginal misfit on the clinical outcome is clearly lacking.[18] Only

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

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Clinical Implications

Using an appropriate completely digital workflow, complete-arch implant-supported prostheses with a better fit than those from conventional impressions can be produced.

mechanical issues related to the screws have been associated with misfit.[18-20] Additional studies with improved designs are needed to determine the impact of misfit on the clinical outcome, the methods of assessing misfit, or whether general or behavioral factors can affect the clinical acceptability of a misfit.[18,20]

The most widely used impression systems are based on elastomeric materials, mainly polyvinyl siloxanes and polyether,[21,22] both of which are uncomfortable for the patient and inconvenient for the dental team to handle. Moreover, elastomeric materials are technique-sensitive, since they involve many steps.[23-28] The accuracy of elastomeric impressions is compromised by connection type,[28] impression technique,[28] and implant angulation.[29] Verification casts and splinting materials are required to achieve clinically acceptable accuracy.[29,30] To improve both patient and dental team experience, several optical scan systems have been developed to increase accuracy.[31] Intraoral scanners (IOSs) provide a standard tessellation language (STL) data set, which allows digital reconstruction of a virtual cast. These systems appear to offer similar results to conventional systems when few and aligned implants are involved.[32] Although IOSs have been suggested as an alternative for complete-arch implant-supported restorations,[33] others have observed significant loss of accuracy with IOSs when more than 3 nonaligned implants were involved and when distances between implants were increased.[34-36]

Other systems can also be used for recording implant location, including stereophotogrammetry[37,38] and cone beam computerized tomography (CBCT),[39] both of which enhance accuracy; however, they require intraoral optical scans or conventional impressions and involve expensive equipment[19] or radiation exposure. To ensure optimal accuracy and to overcome these drawbacks, an auxiliary device has been proposed (medicalfit; DENTALesthetic) (Fig. 1). This device has been claimed to allow correction of the misfit caused by IOSs, thereby optimizing the fit.[40] The approach involves an additional scan of a reference-marked splint of known dimensions to correct deviations with the intraoral optical scan.[40] Custom auxiliary devices have also been proposed to obtain reliable intraoral scans.[41]

The null hypothesis of this pilot clinical study was that the fit of complete-arch implant-supported monolithic zirconia prostheses produced through a completely digital workflow, with the final IOS output corrected with the medicafit device, would be equivalent to the fit of those fabricated from conventional impressions.

Figure 1. medicalfit device has one flat surface (not shown) and another with anatomic forms. Device attached to implant abutments by means of interim abutments.

MATERIAL AND METHODS

This clinical trial was approved by the Ethical Research Committee of Universitat Internacional de Catalunya (REST-ECT-2017-03) and registered at ClinicalTrials.gov (NCT03992300). Twelve consecutive individuals who were ready for complete-arch restorations on 5 to 7 already osseointegrated implants in the maxillary arch were enrolled. All implants had multiunit abutments (Nobel Biocare). Fifteen consecutive patients were selected during the recruitment period from April 2019 to March 2020. Three patients declined to take part in the study after reading the informed consent. The final sample size consisted of 12 participants: one who had 5 implants, 2 with 7 implants, and 9 with 6 implants, for a total of 78 implants. Two records were made for each participant. Record sequence was randomly assigned. Envelopes containing the name of 1 operator and the record sequence were prepared and shuffled, and 1 envelope was selected for each participant.

One record was made by using a conventional impression. Open-tray impression copings (Nobel Biocare) were placed with a torque wrench (Nobel Biocare) set at 10 Ncm on each implant, with the copings splinted by using a light polymerizing clear resin (Triad Gel; Dentsply Sirona), leaving at least a 3-mm diameter around the resin connectors. To avoid structural stress, a 0.3-mm-thick diamond disk (365D fine; Meisinger) was used to section the resin between the 2 connectors. The copings were then reattached with a drop of the same resin. A polyether impression (Impregum; 3M ESPE) was made in a perforated plastic impression tray, and a definitive cast was fabricated in accordance with the

Figure 2. Plaster cast used to verify accuracy of conventional impression.

Figure 3. Intraoral scan with scan bodies in place.

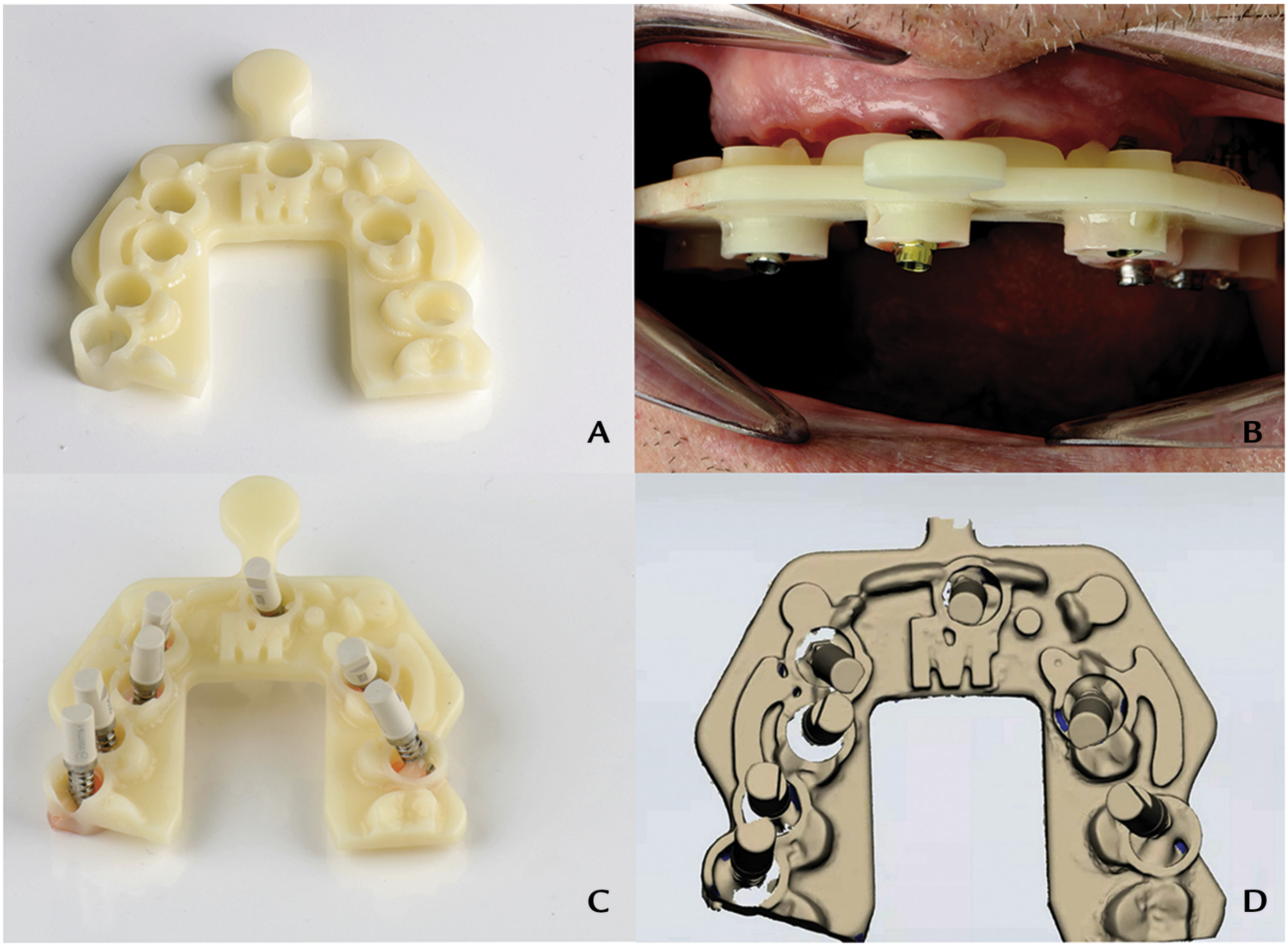

Figure 4. A, medicafit plate trimmed with implant position selected. B, Attached with Triad Gel to interim abutments in mouth. C, Once removed, ScAnalog scannable replicas screwed to interim abutments. D, STL data set obtained with intraoral scanner. STL, standard tessellation language.

manufacturer's instructions. A plaster verification cast (Snow White Plaster No. 2; Kerr Corp) was fabricated on the definitive cast[42,43] (Fig. 2). One week later the vertical dimension of occlusion (VDO) was determined, and the verification cast placed on the implants was used to assess passivity before proceeding to the definitive prosthesis. In the event of verification cast fracture, a new record would have been made.

Figure 5. A, STL data set of medicalfit device scanned with intraoral scanner imported into Meshmixer. B, Each section containing one implant superimposed using best fit tool on STL file of medicalfit device in library. C, Each implant in STL data set obtained using intraoral scanning with scan bodies sectioned. D, Each implant superimposed using best fit tool to its corresponding implant in medicalfit device, yielding final STL file with more accurate position of implants. As shown in image, farther implant from first implant scanned (*), greater required fit. STL, standard tessellation language.

Additional records of the edentulous arch and the antagonist were made by using an IOS (TRIOS3; 3Shape A/S) (Fig. 3). A double scan of the edentulous arch was made, first with the healing abutments in place and then with the scan bodies (Core3D), in accordance with the manufacturer's recommendations. The scan bodies were then removed, and interim copings (Temporary Coping Multi-unit; Nobel Biocare) were screwed onto the multiunit abutments. The medicalfit device was selected, and holes were drilled in the position of each implant to enable the device to fit over the interim copings. The copings were then splinted to the device by using the clear resin (Triad Gel; Dentsply Sirona). After splinting, the medicalfit device was removed and implant replicas (ScAnalog; Dynamic Abutment Solutions) were placed beneath the interim copings on the

Figure 6. Two almost identical prostheses delivered to observers. A, Produced from digital flow. B, Produced from conventional flow.

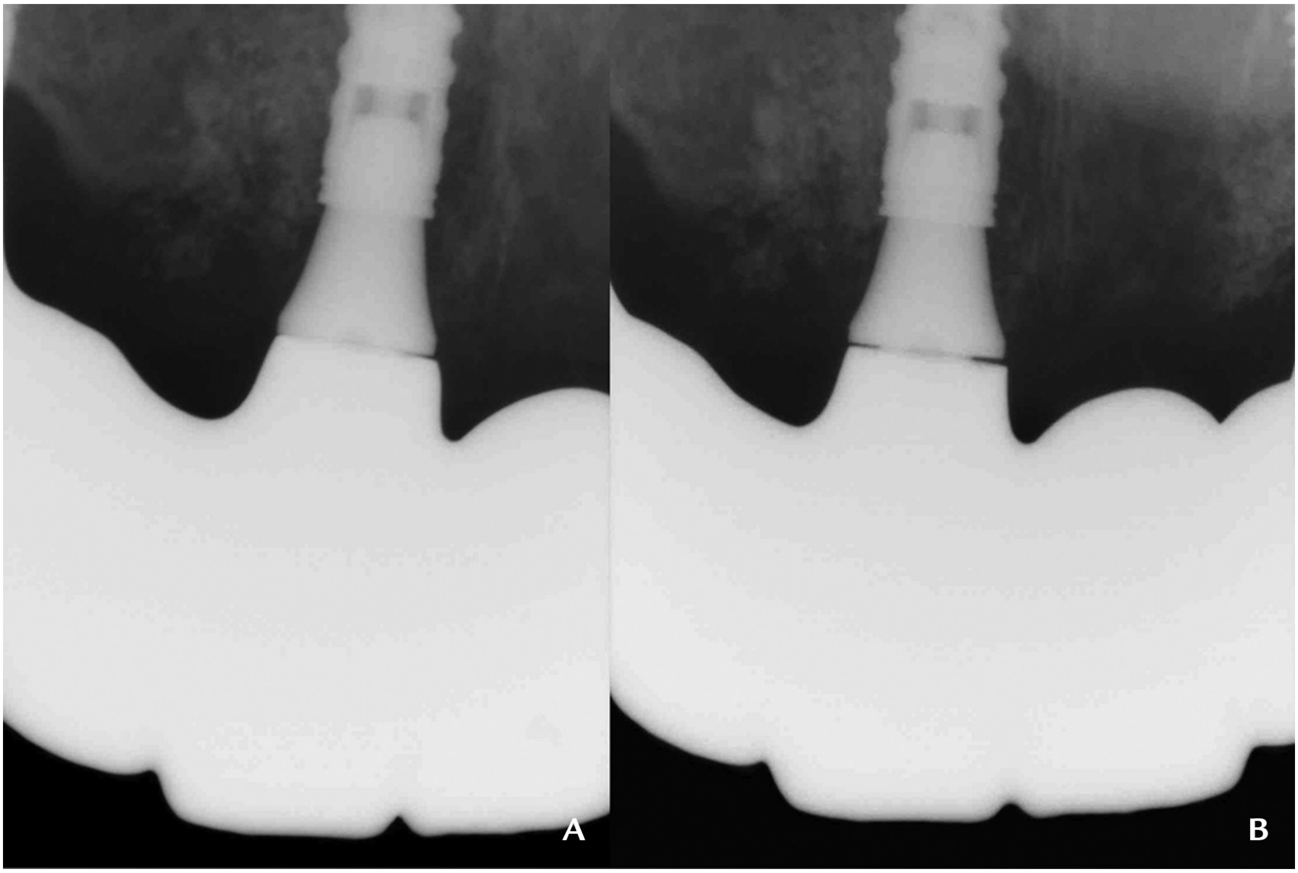

Figure 7. Radiographic assessment of misfit. Although radiographic guide used, perfect alignment of radiographic beam not always possible. A, Digital framework with better fit. B, Conventional framework.

Figure 8. Tightening torque scores. Blue line represents torque and black line indicates time. A, Flat torque line with steep final increase scored 1. B, Initial flat line followed by progressive increase scored 2. C, Early start of increase scored 3.

Table 1. Perception of passivity on visual analog scale (0 cm perfect passivity, 10 cm unacceptable lack of passivity)

Digital/Analog	Examiner	Pt 1	Pt 2	Pt 3	Pt 4	Pt 5	Pt 6	Pt 7	Pt 8	Pt 9	Pt 10	Pt 11	Pt 12
DF	O1	0.25	1.80	0.96	0.48	1.34	1.02	1.11	0.96	0.75	0.86	1.3	0.42
DF	O2	0.72	0.24	0.72	0.52	0.74	1.38	1.92	1.32	1.10	1.14	0.88	0.74
CF	O1	2.40	2.77	5.42	5.36	2.45	1.44	1.33	2.77	2.16	2.4	3.45	2.81
CF	O2	0.24	0.24	7.10	1.36	1.95	1.29	2.32	1.98	3.17	2.93	2.92	1.87

CF, conventional fabrication; DF, digital fabrication; Pt, participant.

Table 2. Signed-rank test for perception of passivity on visual analog scale

Count	12
Mean	2.41
Standard deviation	2.10
Coefficient of variation	87.4%
Minimum	0.38
Maximum	7.65
Range	7.27
Null hypothesis	Median=0
Alternative	Not equal
Average rank of values below hypothesized median	0
Average rank of values above hypothesized median	6.5
Large sample test statistic	3.02 (continued correction applied)
P	.003

Perception of passivity during insertion of prosthodontic screws significantly better in digital than in analog frameworks.

medicalfit device, and intraoral scans were obtained (Fig. 4).

Additional extraoral images of the patient's face were made with the scan bodies in place, at rest, in forced smile, and in the frontal and 45-degree lateral views by using cheek retractors. The images and STL data sets were sent to the dental laboratory technician to fabricate an interim prosthesis. The STL data set from the medicalfit device scan was imported into a 3D image manipulation software program (Meshmixer; Autodesk Inc) and sectioned into as many pieces as the number of implants. The best fit feature was used to superimpose each piece onto the original STL output of the medicalfit device, allowing a more accurate positioning of the implants in the virtual cast (Fig. 5).

At the second appointment, a laboratory-made interim polymethyl methacrylate (PMMA) framework was evaluated intraorally. Adjustments were made to the occlusal and gingival contours and the esthetics. Once these were corrected, a new IOS image was made with the interim framework in the participant's mouth.

At the follow-up visit, 2 independent, blinded, calibrated examiners evaluated 2 similar zirconia prostheses in the patient's mouth (Fig. 6). One framework was fabricated from the conventional cast (CF) and the second with a completely digital workflow (DF). The prostheses were identified only by symbols ("∇" for conventional, "O" for digital) in the distal right molar, whose meaning was unknown to the evaluators.

Fit was assessed according to 5 criteria: perception of passivity during insertion of the prosthodontic screws, tactile perception, radiographic examination findings,[38] Sheffield test results,[20] and tightening torque.[44]

A visual analog scale (VAS) was used to assess the perception of passivity during insertion of the prosthodontic screws. The operator marked the level of passivity on a 10-cm line with one end labeled "perfect passivity" and the other end labeled as "no passivity at all." Thus, the distance between the mark and "perfect passivity" defined the framework passivity.

Marginal fit was examined by using an explorer (Explorer 17-23; LM) under ×3.8 magnification. Three scores were possible: 0 (no gap perceived), 1 (perception of gap without probing), and 2 (the tip of the explorer clearly entered the gap).

After tightening all the screws to 15 Ncm, periapical radiographs were made with a positioner (XCP-ORA; Dentsply Sirona) to detect gaps (Fig. 7). Gaps were assessed from 1 to 5, with 1 being no gap and increasing at 0.15-mm increments until reaching 0.60 mm (score 5).

For the Sheffield test, all the screws except the most distal right screw were loosened. A periapical radiograph was made with a positioning system (XCP-ORA; Dentsply Sirona) to evaluate the gap. Gaps were scored from 1 to 5 as previously.

An additional tightening torque measurement was made on each abutment by using a motor controlled by an iPhone application (iChiropro; Bien-Air Dental USA, Inc). All the screws were hand screwed and then loosened 3 full turns. Subsequently, the torque was set at 15 Ncm and 5 rpm. The most distal right screw was tightened first, followed by the other screws, going from the most mesial left to the most distal left, and then to the adjacent implant until all the screws were tightened. The torque-time diagram of each screw was analyzed to determine whether the level began to rise at the end of, or throughout, the tightening process. Three scores were possible: 1 for a linear value with a sharp rise at the end of the tightening, 2 for mild continuous growth with a steeper rise at the end, and 3 for a steep rise at the beginning of the tightening (Fig. 8).

The 2 operators compared the conventional framework with the digital framework (CF, DF) to select the one with the better overall fit. Where there was disagreement, a consensus was reached regarding which framework to place. The selected framework was then tested for occlusion, phonetics, and esthetic parameters and then delivered. Twelve cards, 6 with letters CF written on top and 6 with letters DF on top, were shuffled. The sequence of the 2 tests was randomly assigned to each patient using the shuffled deck of cards. After each participant, the selected card was discarded.

Since each patient was subject to both conventional and digital techniques, within-patient comparison was used for statistical analysis. The signed rank test was used to evaluate perception of passivity on the visual analog scale, marginal fit, radiographic fit, Sheffield test, and tightening torque. When superiority was rejected, a noninferiority test for comparison of paired samples was used. A binomial test was used to evaluate

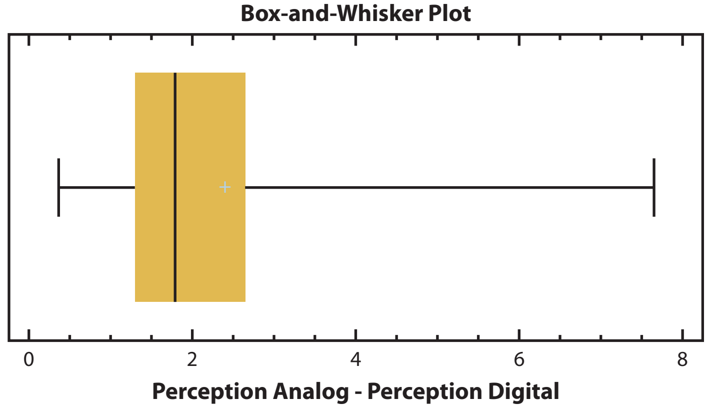

Figure 9. Box-and-whisker plot for perception of passivity on visual analog scale and signed-ranked test. All differences between perception in analog and digital tests positive (worse values in analog group in all participants).

Table 3. Marginal fit on scale from 0 to 2, where "0" represents no gap perceived with explorer, and "1" indicates gap perceived without explorer entering the gap

Digital/Analog	Examiner	Pt 1	Pt 2	Pt 3	Pt 4	Pt 5	Pt 6	Pt 7	Pt 8	Pt 9	Pt 10	Pt 11	Pt 12
DF	O1	0	0	0	0	0	0	0	0	0	0	0	0
DF	O2	0	0	0	1	0	0	1	0	0	0	0	0
DF	FD	0	0	0	1	0	0	1	0	0	0	0	0
CF	O1	0	0	1	1	1	0	0	0	1	0	1	0
CF	O2	0	1	1	1	0	0	0	1	0	1	1	0
CF	FD	0	0	1	1	1	0	0	1	0	1	1	0

CF, conventional fabrication; DF, digital fabrication; FD, final decision by 2 operators when different values determined; Pt, participant.

whether the proportional preference for digital scanning was significantly different from 0.5. Statistical power of the results was measured with a sample size and power calculator (GRANMO; Institut Municipal d'Investigació Mèdica).

RESULTS

None of the gypsum verification devices fractured, and none of the frameworks processed on the intraoral scan and corrected with the auxiliary device had a fit inferior to those processed on the cast and obtained from the conventional impression. All the prostheses were considered clinically acceptable by the observers.

Table 1 shows the results obtained for perception of passivity on a VAS during insertion. The signed-rank test showed statistically significant differences between the 2 systems (Table 2). Figure 9 shows a graphic representation of the distribution of the differences between perception of passivity on a VAS in the analog and in the digital frameworks, with all the differences positive (worse perception of passivity in all frameworks processed from analog impressions). Statistical power of the results was over 80%.

Table 3 shows the results for the examination of the marginal fit with an explorer. The signed-rank test did not reject the hypothesis that the scores for the marginal fit with an explorer were independent of the system used at the 95% confidence level. Better marginal adaptation with DF than with CF was rejected. Noninferiority of marginal adaptation with DF versus CF was demonstrated (Table 4).

Table 5 shows the results of the radiographic fit. The signed-rank test rejected the hypothesis that the scores

Table 4. Noninferiority of digital versus conventional frameworks in marginal fit assessment demonstrated

Sample Statistics					
Sample	N	Minimum	Maximum	Mean	Std. Deviation
Digital MF	12	0	1	0.17	0.39
Analog MF	12	0	1	0.5	0.52

Equivalence Analysis				
Comparison	n	Difference	Standard Error	Upper 95% CL
Digital MF vs Analog MF	12	-0.33	0.19	0.004

Comparison	Upper *t*-Value	Upper *P* Value
Digital MF vs Analog MF	-7.09	0

Comparison	Maximum *P* Value
Digital MF vs Analog MF	0

Comparison	Conclusion (alpha=5%)
Digital MF vs Analog MF	Noninferiority demonstrated

MF, manufacturer.

Table 5. Radiographic fit rated from 1 (no gap) to 5 (gap>.60 mm)

Digital/Analog	Examiner	Pt 1	Pt 2	Pt 3	Pt 4	Pt 5	Pt 6	Pt 7	Pt 8	Pt 9	Pt 10	Pt 11	Pt 12
DF	O1	1	1	1	1	1	1	3	1	1	1	1	1
DF	O2	1	1	1	1	1	1	3	1	1	1	1	1
DF	FD	1	1	1	1	1	1	3	1	1	1	1	1
CF	O1	2	2	2	1	2	1	2	2	2	1	2	1
CF	O2	3	2	2	1	1	1	2	1	2	2	2	1
CF	FD	2	2	2	1	2	1	2	2	2	2	2	1

CF, conventional fabrication; DF, digital fabrication; Pt, participant. Two observers had to agree on results for each assessment (FD).

for radiographic fit were independent of the system used at the 95.0% confidence level (DF better than CF) (Table 6).

Table 7 shows the results for the Sheffield test. The signed-rank test rejected the hypothesis that the scores were independent of the system used at the 95.0% confidence level (DF better than CF) (Table 8).

Table 9 shows the results for the tightening torque. The signed-rank test did not reject the hypothesis that the scores for the tightening torque were independent of the system used at the 95.0% confidence level. Non-inferiority for tightening torque with DF versus CF was demonstrated (Table 10).

Table 11 shows the results for overall performance. Since the *P* value for the binomial test was less than .05 (.003), the hypothesis that the scores were independent of the system used was rejected at the 95.0% confidence level.

Table 6. Signed-rank test for results of radiographic examinations

Count	12
Average	0.58
Standard deviation	0.67
Coeff. of variation	114.61%
Minimum	-1.0
Maximum	1.0
Range	2.0
Null hypothesis	Median=0
Alternative	No equal
Average rank of values below hypothesized median	5.0
Average rank of values above hypothesized median	5.0
Large sample test statistic	2.27 (continued correction applied)
P	.023

Radiographic fit significantly better in digital than in analog frameworks.

DISCUSSION

All the prostheses in this study were placed on multiunit abutments. The results might have been adversely affected had the framework had been placed directly on the implants, since the use of abutments improves accuracy and reduces misfit.[28] The use of titanium bases (ti-bases) between the framework and multiunit abutments requires manual setting and luting of the ti-base, which can induce misfit; therefore, this was avoided. Hence, the zirconia framework was directly seated on the multiunit abutments. To increase framework resistance to tightening torque, the zirconia width in the screw setting was increased, and longer screws were used. Wear of the titanium abutments is one possible complication in this type of framework,[7] but to better determine the fit of the frameworks, it was decided to avoid the use of ti-bases.

The medicalfit concept is somewhat similar to that described by Iturrate et al,[41] which is based on a double IOS protocol, one with regular scan bodies and one with an auxiliary device that is designed after the first IOS output is obtained, 3D-printed, and then luted to the scan bodies. The auxiliary device, on account of its anatomic landmarks, allows better superimposition of the images obtained from the IOS, thereby improving the accuracy of the system.[41] The medicalfit device thus seems to offer several advantages as a prefabricated device, and it is luted to conventional interim copings. However, with the proposed assessment methods, it was not possible to control vertical discrepancies. Although radiographic assessment can be precise when the radiographic beam is perpendicular to the implant long axis, it is clinically impossible to ensure perfect perpendicularity.[39]

Since ScAnalog replicas are made from polyetheretherketone (PEEK), proper care must be taken when tightening to avoid damage to the threads and incorrectly positioning the replica. This may explain the discrepancy in 1 of the implants in participant 7's DF prosthesis, and it also may have been responsible for the poorer results obtained with the digital system for that participant, which was the only treatment that showed worse results than the analog system. It might also explain how 1 implant in participant 7, with a score of 3 in the radiographic fit, had a corresponding score of 1 in the Sheffield test.

The use of complete-arch zirconia frameworks can be successful, provided the fit on the implant abutments is good[7] and accuracy comparable with that of titanium frameworks can then be achieved.[10] Zirconia frameworks flex less and are more likely to fracture because of stress.

Table 7. Sheffield test results

Digital/Analog	Examiner	Pt 1	Pt 2	Pt 3	Pt 4	Pt 5	Pt 6	Pt 7	Pt 8	Pt 9	Pt 10	Pt 11	Pt 12
DF	O1	1	3	1	1	2	2	1	1	1	1	2	1
DF	O2	2	1	1	1	1	1	1	1	1	2	1	1
DF	FD	2	2	1	1	1	2	1	1	1	1	2	1
CF	O1	2	3	5	1	3	3	2	3	2	2	3	2
CF	O2	3	2	3	3	2	3	2	3	2	2	3	1
CF	FD	2	3	3	2	3	3	2	3	2	2	3	2

CF, conventional fabrication; DF, digital fabrication; Pt, participant. Scores ranged from 1 (no gap) to 5 (gap>.60 mm) with increments of 0.15 mm between each score. Where 2 observers did not obtain same result, discussed until final score (FD) agreed.

Table 8. Signed-rank test for results of Sheffield test

Count	12
Average	1.17
Standard deviation	0.58
Coeff. of variation	49.5%
Minimum	0
Maximum	2.0
Range	2.0
Null hypothesis	Median=0
Alternative	No equal
Average rank of values below hypothesized median	0
Average rank of values above hypothesized median	6.0
Large sample test statistic	3.02(continued correction applied)
P	.002

Sheffield test significantly better in digital than in analog frameworks.

Table 9. Tightening torque results

Tightening Torque (1-3)													
Examiner	Digital/ Conventional Fabrication	Pt 1	Pt 2	Pt 3	Pt 4	Pt 5	Pt 6	Pt 7	Pt 8	Pt 9	Pt 10	Pt 11	Pt 12
O1	DF	2	1	2	1	1	1	3	2	1	2	2	1
O2	DF	1	1	1	2	2	1	2	1	2	2	2	1
FD	DF	2	1	2	1	2	1	3	2	1	2	2	1
O1	DF	3	3	2	3	2	2	1	2	3	2	3	2
O2	DF	2	1	2	3	1	3	2	2	2	2	3	2
FD	DF	2	2	2	3	2	2	2	2	2	2	3	2

CF, conventional fabrication; DF, digital fabrication; Pt, participant. Scores ranged from 1 (excellent) to 3 (regular). Where 2 observers did not obtain same result, discussed until final score (FD) agreed.

Table 10. Noninferiority of digital versus conventional frameworks in tightening torque assessment demonstrated

Sample Statistics					
Sample	N	Minimum	Maximum	Mean	Std. Deviation
Digital ST	12	1.0	3.0	1.67	0.65
Analog ST	12	2.0	3.0	2.17	0.39

Equivalence Analysis				
Comparison	n	Difference	Standard Error	Upper 95% CL
Digital ST versus Analog ST	12	-0.5	0.23	-0.086

Comparison	Upper *t* Value	Upper *P* Value
Digital ST versus Analog ST	12	-0.5

Comparison	Maximum *P* Value
Digital ST versus Analog ST	12

Comparison	Conclusion (α=.05)
Digital ST versus Analog ST	12

Table 11. Overall performance results

Examiner	Pt 1	Pt 2	Pt 3	Pt 4	Pt 5	Pt 6	Pt 7	Pt 8	Pt 9	Pt 10	Pt 11	Pt 12
O1	DF	DF	DF	DF	DF	DF	CF	DF	DF	DF	DF	DF
O2	DF	DF	DF	DF	DF	DF	CF	DF	DF	DF	DF	DF
FD	DF	DF	DF	DF	DF	DF	CF	DF	DF	DF	DF	DF

CF, conventional fabrication; DF, digital fabrication; Pt, participant. Sample proportion=0.92; sample size=12; *P*=.003; null hypothesis: theta=0.05; alternative hypothesis: theta >0.5. Values of theta supported by data >0.66. Scores ranged between DF (digital) and CF (analog). Where 2 observers did not obtain same result, discussed until final score (FD) agreed. Binomial test rejected that results independent of technique (*P*<.05).

Discrepancies of up to 500 μm can disappear when the screws are tightened, even in stiff frameworks, generating stress within the framework.[19] In the case of misfit, the stiffer the material, the greater the stress experienced by the framework,[19] although the impact of stress on the framework and the implants has not been clearly demonstrated.[18-20]

The participants received different numbers of implants. In treatments with fewer implants, the distance between implants was greater, which might have caused problems for intraoral impression making.[36] Nevertheless, a clinically acceptable fit was found in all the digital treatments, probably because the use of the auxiliary device improved the accuracy of the IOS output.

Angulation of multiunit abutments varied significantly across patients. Although increased angulation might represent a problem of accuracy, it has been demonstrated that even if the angulation is as high as 20 degrees, framework fit can be achieved, provided a verification cast is used.[29] In order to ensure maximum accuracy, a verification cast was used in the CF treatments.[29] No fractures were observed in the verification cast, implying that the splinting protocol of the open-tray impressions was accurate. Nevertheless, given the high cost of zirconia frameworks, the limited number of participants evaluated meant it was difficult to determine whether it is reasonable to avoid a verification cast if good splinting has been performed. Triad Gel was used for splinting in this study. Although other materials have been reported to be more accurate,[30] from a clinical perspective, the ease of using Triad Gel makes it more suitable for all situations,[29] and it offers acceptable precision and trueness.[29] No fractures occurred in the gypsum verification cast, showing that Triad Gel is an acceptable material for splinting.

Misfit should be ideally below 10 μm,[15] but clinical fit is difficult to assess from conventional or quantitative methods.[16,17,19] When using tightening torque to evaluate fit, it is advisable to measure the torque and angle of rotation of the screw.[44] In the present study, time instead of the angle of rotation was used. Since the rotating speed was constant (iChiropro also registers rotational speed), time also represents the angle of rotation and can be used for torque-angle signature analysis.

In the present study, tightening torque showed more passivity in 9 of the 14 digitally processed frameworks, and less passivity in only 1, but a larger sample size would be necessary to confirm the superiority of 1 of the 2 systems in achieving passivity. Further studies are also required to address chair time, dental team experience, patient experience, and overall cost.

CONCLUSIONS

Based on the findings of this pilot clinical study, the following conclusion was drawn:

1. The use of a prefabricated auxiliary device after intraoral scanning allowed delivery of complete-arch implant-supported monolithic zirconia prostheses with a fit better than those fabricated from conventional impressions.

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Acknowledgments
The authors thank Mr Pedro Perales Pulido, DT and Mr Pedro Perales Padilla, DT for their help in laboratory procedures.

https://doi.org/10.1016/j.prosdent.2020.10.024