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CLINICAL RESEARCH

A combined digital and stereophotogrammetric technique for rehabilitation with immediate loading of complete-arch, implant-supported prostheses: A randomized controlled pilot clinical trial

María Peñarrocha-Diago, PhD,[a] José Carlos Balaguer-Martí, DDS,[b] David Peñarrocha-Oltra, PhD,[c] José Francisco Balaguer-Martínez, PhD,[d] Miguel Peñarrocha-Diago, PhD,[e] and Rubén Agustín-Panadero, PhD[f]

ABSTRACT

Statement of problem. Traditional impressions for complete-arch restorations are complex and time-consuming, and they can be uncomfortable for the patient. New digital techniques such as stereophotogrammetry may mitigate this.

Purpose. The purpose of this randomized controlled pilot clinical trial was to compare the patient and dentist satisfaction and work times of traditional impressions (control group) and digital impressions with stereophotogrammetry in complete-arch, implant-supported prostheses. Success rates, implant survival, marginal bone loss around the dental implants, and prosthesis survival were also analyzed.

Material and methods. This randomized controlled pilot clinical trial included 18 participants who received 131 dental implants. Implant impressions in the experimental group were made with stereophotogrammetry (8 participants with 66 implants), while traditional impressions were made in the control group (10 participants with 65 implants). Working times were measured in minutes starting from removal of the healing abutments to their replacement after the impression. Patient and dentist satisfaction was analyzed using a questionnaire with a visual analog scale, and implant success was assessed using the Buser success criteria. Prosthesis survival was defined as the presence of the prosthesis in the mouth, without screw loosening or fracture.

Results. The work times were 15.6 (experimental group) and 20.5 minutes (control group) ($P<.001$). The patient satisfaction scores were 8.8 in the experimental and 7.9 in the control group ($P=.02$). The dentist satisfaction scores were 9.1 in the experimental group and 8.5 in the control group ($P=.03$). The implant success rate was 100% in both groups. Marginal bone loss was 0.6 ±0.5 mm (experimental group) and 0.6 ±0.2 mm (control group) ($P=.72$).

Conclusions. Digital impressions using stereophotogrammetry may be an alternative to traditional impressions. Patient and dentist satisfaction improved, and the work time was reduced in the experimental group. No statistically significant differences were found in terms of the implant success rate, implant survival, marginal bone loss, or prosthesis survival between the 2 groups. (J Prosthet Dent 2017;■:■-■)

Stereophotogrammetry could be incorporated into dental practice, where it can be used for digital impressions in restorations involving complete-arch, implant-supported fixed prostheses.[1] In conventional digital impression techniques, as the number of implants to be included in the impression increases, precision decreases, since the individual measurement error for each of them is cumulative.[2] Computer-assisted design and computer-assisted manufacturing (CAD-CAM) processing can reduce human error and improve the fit of the prosthesis,[3-5] but impressions still have a margin of error in the position of the implants,[2] particularly with complete-arch restorations. Such problems are reduced with photogrammetry[6] because the discrepancies with this technique are small; they

[a]Assistant Professor, Valencia University Medical and Dental School, Valencia, Spain.
[b]Postgraduate student, Department of Stomatology, Valencia University Medical and Dental School, Valencia, Spain.
[c]Associate Lecturer, Department of Stomatology, Valencia University Medical and Dental School, Valencia, Spain.
[d]Associate Professor, Valencia University Medical and Dental School, Valencia, Spain.
[e]Chairman and Director, Department of Oral Surgery and Implantology, Valencia University Medical and Dental School, Valencia, Spain.
[f]Associate Professor, Department of Stomatology, Valencia University Medical and Dental School, Valencia, Spain.

Clinical Implications

Photogrammetry systems may allow the reliable digital registration of multiple implants for rehabilitation with complete-arch fixed implant prostheses.

have been reported to be 5 μm[2] to 5.6 μm[7] or as little as 4 μm[8] under favorable conditions.

The analog transfer of information to the dental laboratory on the position and angulation of implants with elastomeric impression materials results in errors in each of the phases of the process because of contraction of the materials, bubbles and distortions during impression making,[9,10] preparation of the casts, and waxing. For this reason, new techniques are being introduced,[11] including digital impressions, because information can be transferred directly without the need for prior processing steps.[11,12] Digital impressions may be more comfortable for the patient and reduce work times.[13-17]

To date, the systems used for the digital impression of implants have failed to reach the precision of the traditional impression techniques, particularly for complete-arch restorations with several implants.[18-20] Although these discrepancies might not be clinically relevant, provided a proper digital impression technique is used,[21] photogrammetry-based digital impression techniques offer great precision, even in making impressions of multiple implants.[1,21] However, unless a CAD-CAM prosthesis is provided, definitive casts are still needed for laboratory procedures with this technique.[22] A number of articles have been published on impression making with stereophotogrammetry, although each report involved only a single participant.[1,11,22-24]

Therefore, the purpose of this pilot study was to evaluate the advantages and disadvantages of making digital impressions using photogrammetry by analyzing the work times, patient and dentist satisfaction, the success rates and marginal bone loss of the implants, and the survival of the prosthesis. The null hypothesis was that conventional and stereophotogrammetric impressions would show no differences in work times, patient or dentist satisfaction, success rates, or marginal bone loss.

MATERIAL AND METHODS

A randomized, controlled clinical pilot trial was designed involving participants provided with maxillary or mandibular complete-arch, implant-supported prostheses between January 2014 and September 2014 in the Oral Surgery Unit (Valencia University Medical and Dental School, Valencia, Spain). The present investigation was approved by the ethics committee of the University of Valencia (H1434637970504). All participants signed an informed consent form.

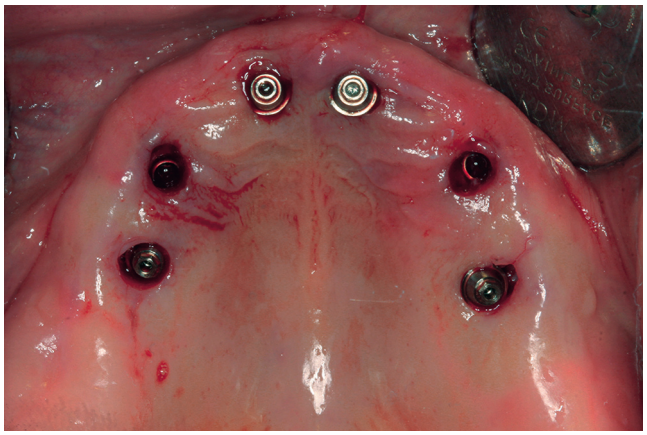

Figure 1. Intermediate abutments screwed to implants, maxilla.

To be included, participants had to be over 18 years of age, seen in the clinic, and in need of complete-arch, implant-supported fixed prostheses without bone augmentation. Excluded were individuals receiving intravenous bisphosphonate or monoclonal antibody therapy, individuals with uncontrolled bleeding disorders, recent (less than 1 year) acute myocardial infarction or stroke, immunocompromised individuals, individuals with uncontrolled diabetes or hypertension, individuals with malignant disease under treatment or with systemic disease contraindicating dental surgery, bruxist individuals, individuals with complete denture antagonists, and individuals in whom it was not possible to record all the necessary variables for the investigation. Two parallel groups were established: experimental and control. The experimental group included 8 participants (3 men and 5 women, with a median age of 60.5 years [range 37 to 65 years]), each of whom received a treatment plan for a complete-arch, implant-supported prosthesis with the work flow based on the stereophotogrammetry recording of the 3-dimensionsal (3D) spatial orientation of their implant positions. The control group (6 men and 4 women with a median age of 58 years [range 41 to 69 years]) received similar treatment but had their implant positions recorded with conventional impressions. Simple randomization of the 2 groups was carried by IBM SPSS v20 software (IBM Corp) using a macro (!RNDSEQ)[25] in the same way as Pastor et al.[26] The investigators (B.M.J., A.P.R.) and the statistician were blinded to the allocation of the participants.

Dental implants (InHex; Ticare, Mozo-Grau) were placed by an experienced surgeon (P.D.M.) following the manufacturer's guidelines. The participants were anesthetized with an articaine 4% and epinephrine 1:100 000 anesthetic solution (Artinibsa; Inibsa), and a

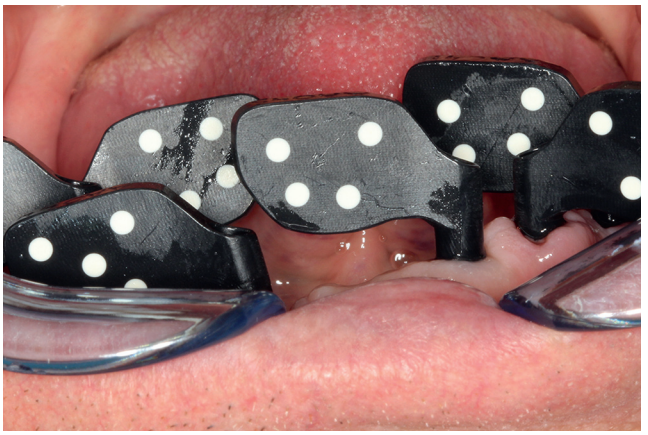

Figure 2. PIC abutments attached to implants for impression making.

Figure 3. Digital impression made with PIC Camera.

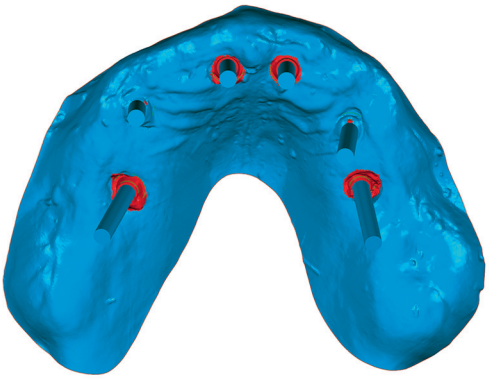

Figure 4. Maxillary implants positioned in digital casts after best-fit soft tissue superimposition, occlusal view.

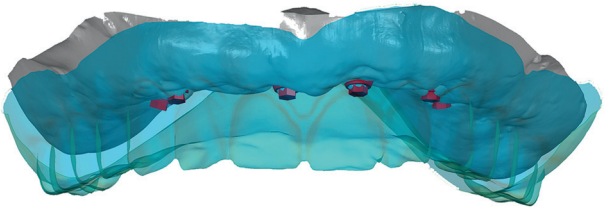

Figure 5. Digital design of prosthesis.

mucoperiosteal flap was raised. The implant bed was prepared following the drilling protocol of the manufacturer. The flap was then sutured with 5-0 polyamide (Polimid; Sweden & Martina).

In the experimental group, after implant placement (Fig. 1), healing abutments were screwed onto the implants for immediate loading, their height was recorded, and an impression was made with irreversible hydrocolloid (Hydrogum 5; Zhermack) to register the soft tissue contours. The impressions were poured with Type 4 gypsum (Elite Master; Zhermack) and digitalized with a 3D scanner (Rexcan Ds3; Solutionix). Then the arch in which the implant impression was to be made was entered in the software of the camera (PIC Camera; PIC Dental), and the scan bodies (PIC abutment; PIC Dental) were screwed into the implants for impression making (Fig. 2). The impressions were made with the camera, which consisted of 2 infrared charge-coupled device cameras (Fig. 3) that registered the distance and angulation between the scan bodies. The cameras registered 50 images for every 2 abutments. The system was able to obtain 600 images in under 60 seconds.

The position of the implants registered with the camera was aligned and merged with the digitized casts of the irreversible hydrocolloid impression using a computer program (DentalCAD; exocad) and performing best-fit automatic adjustment (Figs. 4-6). To determine the vertical dimension and clinically assess a trial tooth arrangement, a physical definitive cast (or virtual articulator) is required. A 3D printer (Objet Eden 260VS; Stratasys) was used for this purpose. The metal framework of the prosthesis was designed digitally and filed in open 3D standard tessellation language (STL) format (Figs. 6, 7). It was designed from an STL file that combined both the position of the implants and the soft tissues. A cobalt–chromium alloy was used (Colado CC; Ivoclar Vivadent AG). A 3D stereolithographic cast was printed for placement of the ceramic.

The correct passive fit of the metal to the implant connection was evaluated from periapical radiographs,

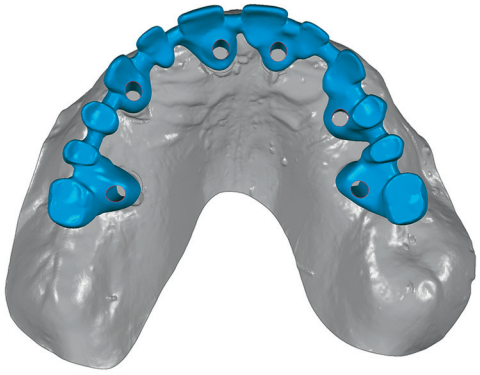

Figure 6. Digital design of CAD-CAM milled framework. CAD-CAM, computer-aided design and computer-aided manufacturing.

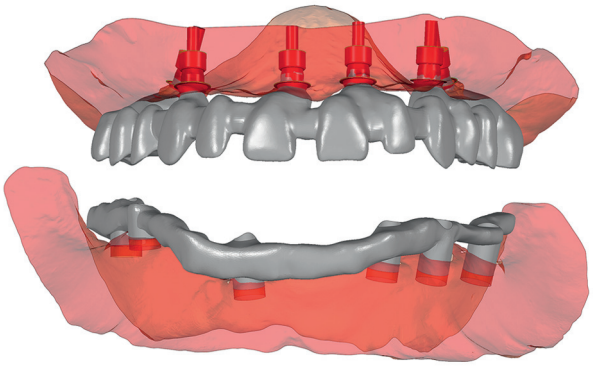

Figure 7. Metal frameworks of both arches in digital casts, frontal view.

the Sheffield test, and the screw resistance test.[1] The periapical radiographs were standardized with polyvinyl siloxane occlusal registrations and cone paralleling rings (Rinn XCP; Dentsply Intl). Vertical dimension was registered with record bases. In a full-digital protocol, digital facial arcs can be used instead of recording bases to assess the vertical dimension. The prosthesis was sent to the laboratory for layering with feldspathic porcelain (IPS d.SIGN; Ivoclar Vivadent AG) on a 3D printed stereolithographic cast. Finally, the completed prosthesis was screwed to the implants with a torque of 30 Ncm (Fig. 8). Participants were followed up for a minimum of 1 year after loading. Panoramic radiographs at loading and after 2 years of follow-up are shown in (Fig. 8D, E).

In the control group, the impression copings were first screwed to the implants, and periapical radiographs were used to evaluate correct fit to the implant connection. The impression copings were splinted with autopolymerizing acrylic resin (Pi-Ku-Plast; Bredent), waiting 7 minutes for the resin to polymerize. Then impressions were made with polyether material (Impregum Penta; 3M ESPE) in a perforated tray using the open tray direct technique.[3] An impression was made with irreversible hydrocolloid. It was sent to the laboratory to make a custom tray with perforations at the implant locations. Polyether adhesive (Impregum Penta; 3M ESPE) was applied to the tray before making the impression. After 6 minutes, the impression copings were unscrewed from the implants, and the tray was removed. It was evaluated to determine whether the impression material had correctly registered the periimplant soft tissues, and the impression was sent to the laboratory for preparation of the definitive cast. The cast was digitalized to create the prosthesis using CAD-CAM. The passive fit of the metal to the implant connection was evaluated from periapical radiographs, the Sheffield test, and the screw resistance test.[1] The vertical dimension of occlusion was registered with record bases and occlusion rims. After confirming the correct fit, the prosthesis was sent to the laboratory for layering with feldspathic porcelain. Finally, the completed prosthesis was screwed in place with a torque of 30 Ncm.

The following parameters were analyzed: age, sex, maxillary or mandibular prosthesis, time spent making the impressions, patient satisfaction, dentist satisfaction, marginal bone loss, and the implant success rate after 1 year of loading. Time was measured in minutes, counting from the removal of the healing abutments for making the impressions to replacement of the healing abutments.

Patient and dentist satisfaction was evaluated with a questionnaire using a visual analog scale in the form of a 10 cm horizontal line, where 0 (left end) indicated minimum satisfaction and 10 (right end) indicated maximum satisfaction. The scale was analog, without intermediate divisions, and the participants were instructed to mark the position considered to best represent their degree of satisfaction. The investigator subsequently measured the score in millimeters from the left end of the line to the marked point.

Marginal bone loss was measured using the imaging software (DBSWIN Imaging Software; DürrDental), establishing 2 arbitrary points at the platform interface to trace a straight line. Two straight lines were then traced perpendicular to this first line, both mesial and distal to the implant, to the first bone–implant contact. The difference between the measurements made immediately after surgery and after 12 months of follow-up defined the mean marginal bone loss. In all situations, the highest of the values calculated for mesial or distal were selected.[27] The implant success rate in turn was evaluated on the basis of the criteria of Buser et al.[28] Prosthesis survival was defined as the presence of the prosthesis in the mouth, without screw loosening or fracture.

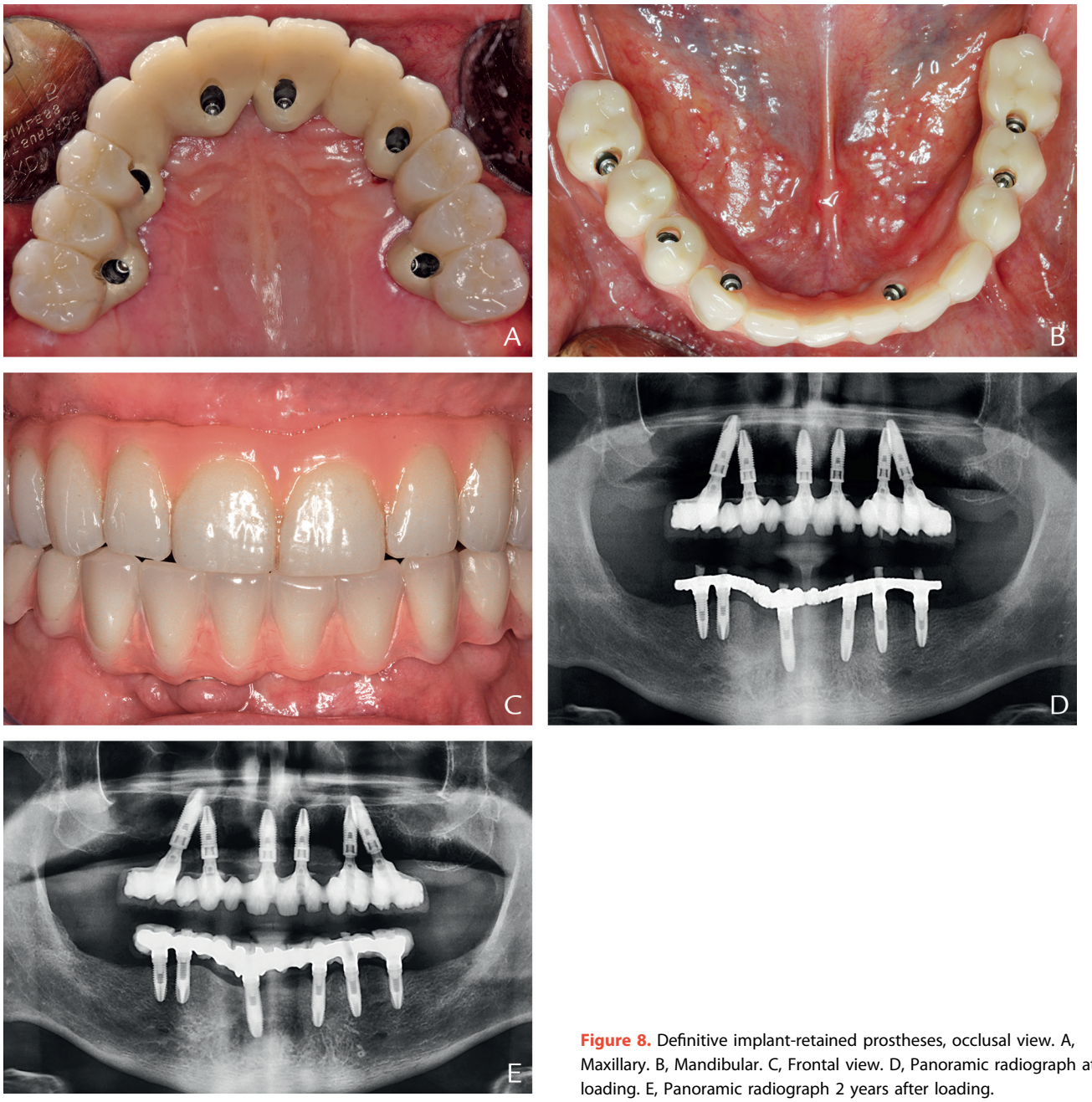

Figure 8. Definitive implant-retained prostheses, occlusal view. A, Maxillary. B, Mandibular. C, Frontal view. D, Panoramic radiograph at loading. E, Panoramic radiograph 2 years after loading.

The statistical analysis was carried out by IBM SPSS Statistics v20 statistical software (IBM Corp), calculating the basic statistical values of the continuous and ordinal variables (mean, SD, minimum, maximum, and median). The normality of data distribution was assessed using the Shapiro-Wilk test. For comparison purposes, in the case of continuous variables with a normal distribution, use was made of the Student *t* test, while variables exhibiting a nonnormal distribution were analyzed using the Mann-Whitney *U* test. In the case of categorical variables with a normal distribution, use was made of the chi-square test. The Fisher exact test in turn was applied in the case of a nonnormal distribution (α=.05).

RESULTS

Two participants were lost in the digital impression group, one because of a lack of follow-up and the other because of an incomplete protocol. A total of 8 participants were included in the experimental group and 10 in

Table 1. Description of participants

Participant No.	Age (y)	Sex	No. of Implants	Arch	Follow-up (mo)	MBL (mm)	Work Time (min)	Patient Satisfaction	Professional Satisfaction	Group
1	63	M	6 max, 6 mand	Both	12	0.4	15.7	8	9	Exp
2	37	F	4 mand	Mand	12	1.3	14.2	9	8	Exp
3	59	F	8 max, 4 mand	Both	12	1.7	17.6	9	9	Exp
4	62	F	7 max	Max	25	0.5	14.6	10	10	Exp
5	62	F	5 max	Max	14	0.4	17.3	9	9	Exp
6	52	M	8 max	Max	12	0.3	14.9	9	9	Exp
7	54	F	6 max	Max	12	0.3	15.1	9	9	Exp
8	65	M	6 max, 6 mand	Both	12	0.5	15.5	8	10	Exp
9	57	M	6 max	Max	12	0.7	26.3	8	8	Control
10	63	M	6 max	Max	12	0.9	28.2	9	9	Control
11	52	F	6 mand	Mand	12	0.4	25.8	9	9	Control
12	69	M	8 max	Max	23	0.6	26.7	7	8	Control
13	41	M	6 max	Max	12	0.5	27.9	8	8	Control
14	64	M	7 mand	Mand	15	0.3	25.1	7	8	Control
15	53	F	6 max	Max	12	0.9	28.7	9	8	Control
16	55	F	6 max	Max	12	0.3	27.8	7	8	Control
17	61	M	6 max	Max	12	0.8	26.3	7	7	Control
18	59	F	8 max	Max	24	0.6	29	8	8	Control

MBL, marginal bone loss; max, maxilla; mand, mandible; Exp, experimental.

the control group (Table 1), with restoration being carried out in 131 implants. The descriptive statistics are shown in Table 2.

The mean ±SD time required to take the impressions was 15.6 ±1.2 minutes in the experimental group and 27.1 ±1.3 minutes in the control group; the difference was statistically significant (Student *t* test, $P<.001$). The mean ±SD participant satisfaction score was 8.8 ±0.6 in the experimental group and 7.9 ±0.8 in the control group; the difference was statistically significant (Mann-Whitney *U* test, $P=.028$). The mean ±SD professional satisfaction score was 9.1 ±0.5 in the experimental group and 8.5 ±0.5 in the control group; the difference was statistically significant (Mann-Whitney *U* test, $P=.03$). Passive fit using the Sheffield test, screw resistance test, and radiographs proved positive in all restorations in both groups.

The mean ±SD duration of follow-up was 14.7 ±5.2 months, with a periimplant marginal bone loss of 0.6 ±0.5 mm in the experimental group. Two participants in the experimental group presented greater than average periimplant marginal bone loss of 1.3 and 1.7 mm. The mean ±SD bone loss in the control group was 0.6 ±0.2 mm. The differences in periimplant marginal bone loss were not statistically significant (Mann-Whitney *U* test, $P=.72$). The implant success and implant survival rate after 12 months was 100% in both groups. The prosthesis success rate was 100% in both groups, with no screw loosening or fracturing.

Table 2. Participant characteristics

Characteristic	Overall	Stereophotogrammetry Group	Conventional Impression Group
Age (y)	57.1 ±8.5	56.8 ±9.1	57.4 ±7.8
Sex (%)			
Female	66.7	62.5	70
Male	33.3	37.5	30
No. of implants	131	66	65
Average no. of implants per participant	7.3 ±2.4	8.3 ±3.3	6.5 ±0.84
Arch (%)			
Maxilla	66.7	50	80
Mandible	16.7	12.5	20
Both	16.7	37.5	-
Follow-up (mo)	14.3 ±4.6	13.9 ±4.6	14.6 ±4.8
MBL (mm)	0.6 ±0.4	0.7 ±0.5	0.6 ±0.22

MBL, marginal bone loss.

DISCUSSION

Within the limitations of this pilot randomized clinical trial, the data support rejection of the null hypothesis with regard to work time and satisfaction, but not to implant success, survival and marginal bone loss, or prosthesis success. Impressions made with stereophotogrammetry required less work time and afforded greater satisfaction than traditional impressions.

A good fit of the prosthesis may be important for middle- and long-term success.[28] Poor fit of the prosthesis also appears to be a risk factor for periimplantitis and bone loss,[29-31] although minor misfits (100 μm) may be tolerated.[32] To improve fit, great precision is needed in fabricating the prosthesis. The current tendency is to reduce the number of intermediate steps needed to fabricate the prosthesis through CAD-CAM technology, which improves precision[3,4] and survival. Furthermore,

the periimplant marginal bone loss is similar to when transepithelial abutments are used.[5]

To date, no reliable digital methods have been available for making complete-arch implant impressions, with the cumulative error observed to increase with the number of implants.[20] Lee et al[9] analyzed a system for making digital impressions over implants and found that traditional impressions with elastomeric materials offered greater precision than digital impressions along the long axis of the implant, with similar performance in terms of the rest of the studied magnitudes. Stereophotogrammetry has recently been used for making intraoral digital impressions.[1,11] This system affords very high precision, with an error of under 5 μm in in vitro studies[2,7] and of less than 10 μm in in vivo studies, independent of the number of implants involved.[1,11] This allows shortening of the chain of error, thanks to the direct digital transfer of the information from the impressions to drilling of the working cast.[13] Material contraction due to polymerization or CAD-CAM alignment is thereby prevented. However, previous published articles about stereophotogrammetry were in vitro or only included a single participant. Furthermore, these studies concentrated on accuracy, survival, and marginal periimplant bone loss, without considering other important variables such as work time and satisfaction that were assessed in this study.

The time needed for impression making in the present study was shorter with the stereophotogrammetry technique, coinciding with the observations of other authors who likewise recorded shorter times with the digital impressions compared with traditional impressions;[13-16] however, Wismeijer et al[17] recorded the opposite results in their study. An explanation for this paradoxical result is that Wismeijer et al used a closed tray impression technique without splinting the implants. Digital impressions do not use materials that need to polymerize, reducing working time. In the present study, the conventional impression times were much longer than in the aforementioned studies. A possible explanation for this difference is that the impressions were made in participants undergoing restoration with complete-arch prostheses instead of crowns and short-span fixed dental prostheses. Furthermore, the studies that compared digital and conventional impressions failed to specify whether the implants were splinted before impression making.[13,17] Splinting prolongs the time needed to make an implant impression by at least 15 minutes because it is necessary to wait for the resin to polymerize.

Reported satisfaction was high in both groups, thanks to the reduction of participant discomfort associated with impressions using elastomeric materials. The experimental group yielded significantly higher satisfaction scores among both the participants and the professionals, in agreement with the observations of other investigators.[13,14,17] The improved satisfaction may be due to the reduced scanning time, and placement of the scan bodies could be better tolerated than elastomeric materials.

In the present study, no statistically significant differences were found in periimplant marginal bone loss, in implant success and survival rates, or in prosthesis survival between the stereophotogrammetry and conventional impression techniques. A possible explanation may be that prosthesis fit was similar in both techniques,[9] and minor misfits moreover do not affect the long-term outcome.[33]

The limitations of the present investigation include the lack of soft tissue reproduction with the camera system: the cast must be scanned, or an intraoral digital scanner must be used. When the implants have greater proximity or converge, scanning can be done in separate phases, keeping attached at least one PIC abutment already registered in the first phase. Then the PIC abutment in proximity to another implant can be placed in the adjacent implant to register it in a second scanning phase. This is a pilot study on work time and satisfaction using the technique. Further studies are needed to analyze in-mouth precision, with the inclusion of larger samples and the quantification of the fit in clinical conditions.

CONCLUSIONS

Within the limitations of this pilot randomized clinical trial, the following conclusions were drawn:

1. The time needed for impression making was shorter with the stereophotogrammetry technique.
2. Patient and dentist satisfaction was greater with the stereophotogrammetry technique.
3. Stereophotogrammetric and traditional impressions showed no differences in implant survival, marginal bone loss of the implants, or prosthesis survival after 1 year of follow-up.

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Corresponding author:
Dr Miguel Peñarrocha-Diago
Clínicas Odontológicas
Gascó Oliag 1
Valencia
SPAIN
Email: miguel.penarrocha@uv.es