THE JOURNAL OF PROSTHETIC DENTISTRY

CLINICAL RESEARCH

Prospective cohort pilot study of 2-visit CAD/CAM monolithic complete dentures and implant-retained overdentures: Clinical and patient-centered outcomes

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ABSTRACT

Statement of problem. Presently, no studies have evaluated clinical outcomes or patient-centered outcomes for complete dentures fabricated with computer-aided design and computer aided manufacturing (CAD/CAM) technology.

Purpose. The purpose of this prospective cohort pilot study was to evaluate the clinical and patient-centered outcomes for CAD/CAM monolithic dentures fabricated in 2 visits.

Material and methods. Twenty participants with an existing set of maxillary complete dentures opposing either mandibular complete dentures or implant-retained overdentures that required replacement were recruited in this study. A 2-visit duplicate denture protocol was used to fabricate 40 arches of monolithic dentures with CAD/CAM technology. A 100-mm visual analog scale (VAS) instrument was then used to record 12 outcomes at baseline and at 1-year follow-up. Predetermined values were assigned to grade the VAS rating of each outcome as favorable (70.1-100) and unfavorable ($\leq$70). Favorable ratings were sub-divided as excellent (90.1-100), good (80.1-90), and fair (70.1-80). The clinical outcomes were evaluated independently by 2 experienced prosthodontists at baseline and at 1-year follow-up. Patients evaluated the corresponding patient-centered outcomes during the same time intervals. Additional descriptive variables were also recorded. Each clinical and patient-centered outcome was summarized by medians and ranges. Differences in all ratings recorded at baseline and at 1 year were tested by 1-sided sign test (α=.05).

Results. Of 20 participants, 3 were lost to follow-up, and 3 were unsatisfied with the digital dentures and withdrew from the study. These 3 participants were considered treatment failures. Of the 14 remaining participants, 9 had implant-retained mandibular overdentures, and 5 had conventional mandibular complete dentures. For clinical outcomes, the 12 studied outcomes were favorably evaluated by the 2 prosthodontist judges at the 1-year follow-up. Evaluations showed minimal differences between baseline and 1 year. An average of 5 emails (0-11) per patient were sent to the laboratory technicians to communicate the improvisation the CAD design of the dentures. An average of 3.3 denture adjustments were needed after insertion (0-10) during the 1-year period. For patient-centered outcomes, median ratings of all 14 participants indicated each of the 12 studied outcomes was favorable at the 1-year recall. Statistically significant improvements in patient ratings from baseline to 1 year were observed for the absence of denture sore spots and treatment time to make the dentures (P<.05). Minor complications related to loss of retention, excessive wear of teeth and the need for additional visits were observed in 5 participants. No other adverse clinical outcomes related to the CAD/CAM dentures were noted in the 14 evaluated participants, and all dentures were intact and in good condition at the 1-year follow-up.

Conclusions. Clinical and patient-centered outcomes for CAD/CAM monolithic dentures fabricated using a 2-visit protocol were evaluated favorably at a 1-year follow-up. However, the proportion of excellent and good ratings for overall satisfaction and assessment was higher for patients than clinicians. A considerable amount of the clinician's time and effort was devoted to aiding in the digital process for the fabrication of CAD/CAM dentures. (J Prosthet Dent 2016;115:578-586)

Supported by a research grant from the Dean's office, University of Connecticut School of Dental Medicine and, in part, by the Greater New York Academy of Prosthodontics student research grant.

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Clinical Implications

Two-visit CAD/CAM monolithic complete dentures are a viable clinical option for edentulous patients, but clinicians should recognize the need for careful patient selection and additional time for the fabrication process. Improvements in protocols, experience, and the use of a trial denture requiring a third visit may overcome some of the current challenges.

The process of fabricating complete dentures has undergone only minor changes over the past 100 years.[1,2] Almost all published reports regarding denture fabrication refers to what is considered the "conventional" technique,[2] which consists of multiples steps requiring 4 to 5 visits. However, with the advent of computer-aided technology, the treatment of edentulous patients with complete dentures has been improved and simplified and the number of patient visits reduced.[2] Computer-aided technology is an area of dentistry that uses computer skills and software algorithms to facilitate the design and manufacturing of different types of dental restorations.[3] This technology consists of additive manufacturing, such as rapid prototyping, or subtractive manufacturing, such as computerized numerical control (CNC) milling, which has become significantly more popular in prosthodontics over the past 10 years. CNC milling creates an object of specific dimensions by using the images obtained from the digital file and milling or grinding a block of material.[3] Milling strategies and methods have continued to provide more indications and lower costs. Several reports have described the use of CAD/CAM technology for the fabrication of inlays, onlays, crowns, fixed and removable partial dental prostheses, implant abutments, maxillofacial prostheses, and substructures for removable and fixed implant-supported prostheses.[4] However, few reports have described the use of computer-aided technology for complete dentures.[5-12] This is probably because of the inherent nature of fabricating complete dentures, which includes the multiple steps of recording, transferring, evaluating, and creating artificial substitutes for teeth and gingiva.

The first published report of the use of computer-aided technology for complete dentures was in 1994.[4] Since then, different theoretical models and unique protocols for fabricating complete dentures with computer aided technology have been described in the scientific literature by many authors.[5-12] Only recently has computer-aided technology for complete dentures been commercialized, and presently, few commercial manufacturers in the United States offer complete dentures, using either rapid prototyping or CAD/CAM technology.[2] Many of these manufacturers have definitive protocols in place, using exclusive dental materials, techniques, and laboratory support. The first clinical report describing the use of CAD/CAM complete dentures in 2 visits on an edentulous patient was published in 2013.[14] As yet, no clinical trials in the literature have reported on the clinical or patient-centered outcomes of CAD/CAM complete dentures. However, a recent article concluded that the digital denture treatment proved an equally effective and more time-efficient option than the conventional process of denture fabrication in a predoctoral dental education program.[15]

The primary objective of this prospective cohort pilot study was to evaluate the clinical and patient-centered outcomes for CAD/CAM monolithic complete dentures fabricated in 2 patient visits. The secondary objectives were to evaluate any differences in outcome evaluation at baseline (within 1 month of insertion) and at a 12-month follow-up since insertion. An additional objective was to identify any adverse clinical and patient-centered outcomes related to CAD/CAM complete dentures.

MATERIAL AND METHODS

Human subject approval for this study was obtained from the University Institutional Review Board (IRB-13-180-1). All participants provided written informed consent before entering the study. Twenty participants were enrolled in this pilot study based on the criteria described in Table 1. The cohort was defined as completely edentulous patients who presented with a set of complete dentures or implant-retained overdentures that required replacement. The reasons for denture replacement included patient dissatisfaction, tooth wear, and compromised esthetics and function. All prostheses were to be fabricated using a 2-visit protocol for monolithic CAD/CAM complete dentures (Global Dental Science; Global Dental Sciences).[13] To assess the clinical outcomes, 2 board-certified prosthodontists (A.D., T.T.) were recruited as judges, based on the criteria described in Table 1. Institutional review board procedures were followed for the recruitment of all participants into the study.

At the first visit, demographic information for each patient was collected along with the patient's prior denture wearing experience. Two clinicians (D.B., F.K.) were involved in the treatment for all 20 sets of dentures. Both of the treating clinicians had experience in making 1 set of CAD/CAM dentures. As this was a baseline study, the authors arbitrarily categorized participants as early denture wearers if their prior denture wearing experience was less than or equal to 5 years and experienced denture wearers if the prior experience was greater than 5 years. Thereafter, the clinicians assigned the Milus M. House mental classification for each patient according to the standard methods of evaluating the patient's psychological attitude toward denture treatment.[16,17] The

Table 1. Inclusion and exclusion criteria for participants and judges

Criteria	Inclusion Criteria	Exclusion Criteria
Participants	Adults older than 18 years.	Unable to fulfill any of inclusion criteria.
	Edentulous individuals wearing a set of conventional complete dentures or implant-retained overdentures requiring replacement. Reasons for denture replacement included tooth wear and denture stains due to usage and compromised esthetics and function.	Severely atrophic ridges, hypertrophic tissue, or with maxillofacial defects.
	In good general health with healthy oral tissues.	Inability to obtain all of required clinical information in one visit for CAD/CAM denture.
	Ability to participate in the study for 14 months, understand and respond to self-reporting measurement scales and questionnaires.	
	Ability to understand written and verbal English instructions or the ability to bring their own translator.	
	Willing to surrender existing set of complete dentures and only wear monolithic CAD/CAM dentures for at least 1 year.	
Judges	American board-certified prosthodontist with at least 5 years of clinical experience.	Judges unable to fulfill any of inclusion criteria.
	Willing to participate for the duration of the study.	Recognition or relationship with participant.
	No previous exposure or clinical experience with CAD/CAM or other types of digital dentures.	

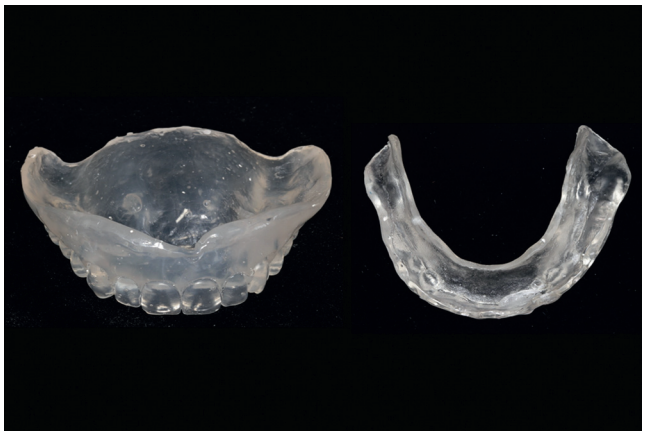

Figure 1. Trimmed and polished clear duplicate dentures before making definitive impression.

duplicate denture protocol introduced by the manufacturer (Global Dental Science) was used to make all records[13] (Fig. 1). Duplicate dentures were then used as a custom tray to accomplish border molding definitive impression procedures using the manufacturer's light-body polyvinyl siloxane material (Global Dental Science) (Fig. 2). If the patient's existing dentures were

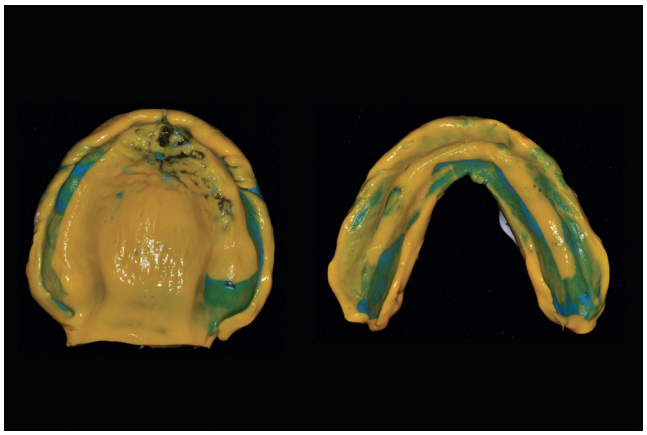

Figure 2. Duplicate dentures used as custom tray to make maxillary and mandibular definitive impressions in polyvinyl siloxane material provided by manufacturer.

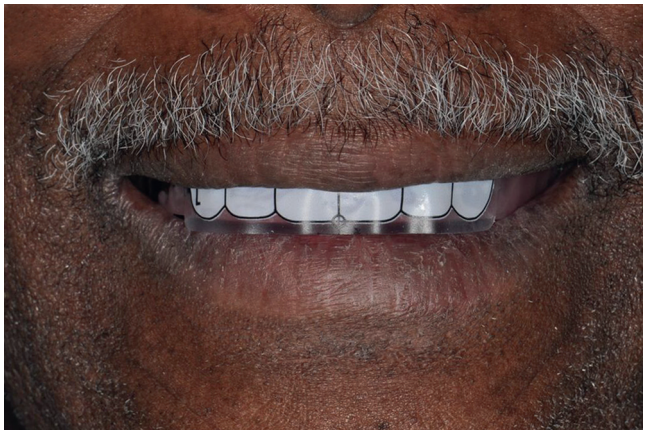

Figure 3. Assessment of maxillary incisal edge position and recording tooth shape and position by affixing clear adhesive strip imprinted with silhouette of selected mold of maxillary anterior teeth.

deemed unsatisfactory because of esthetics or occlusal vertical dimension (OVD), the duplicate denture was trimmed accordingly (either on the labial or occlusal surface), and baseplate wax (Denture Baseplate Wax; Patterson Dental) was added to the trimmed duplicate denture to make an occlusal rim according to the manufacturer's instructions. Duplicate dentures were replaced in the mouth, and lip support, OVD, and maxillomandibular relationships were recorded according to standard prosthodontic principles and techniques.[14] A clear adhesive strip imprinted with the silhouette of the selected mold of maxillary anterior teeth was affixed to the maxillary duplicate denture according to the manufacturer's protocol (Fig. 3). Tooth shade was chosen with the patient's input and recorded. Photographs were made at rest and maximum smile and were sent with both duplicate dentures and interocclusal record registration to the manufacturer's laboratory (Global Dental Science) with the appropriate laboratory work authorization form.

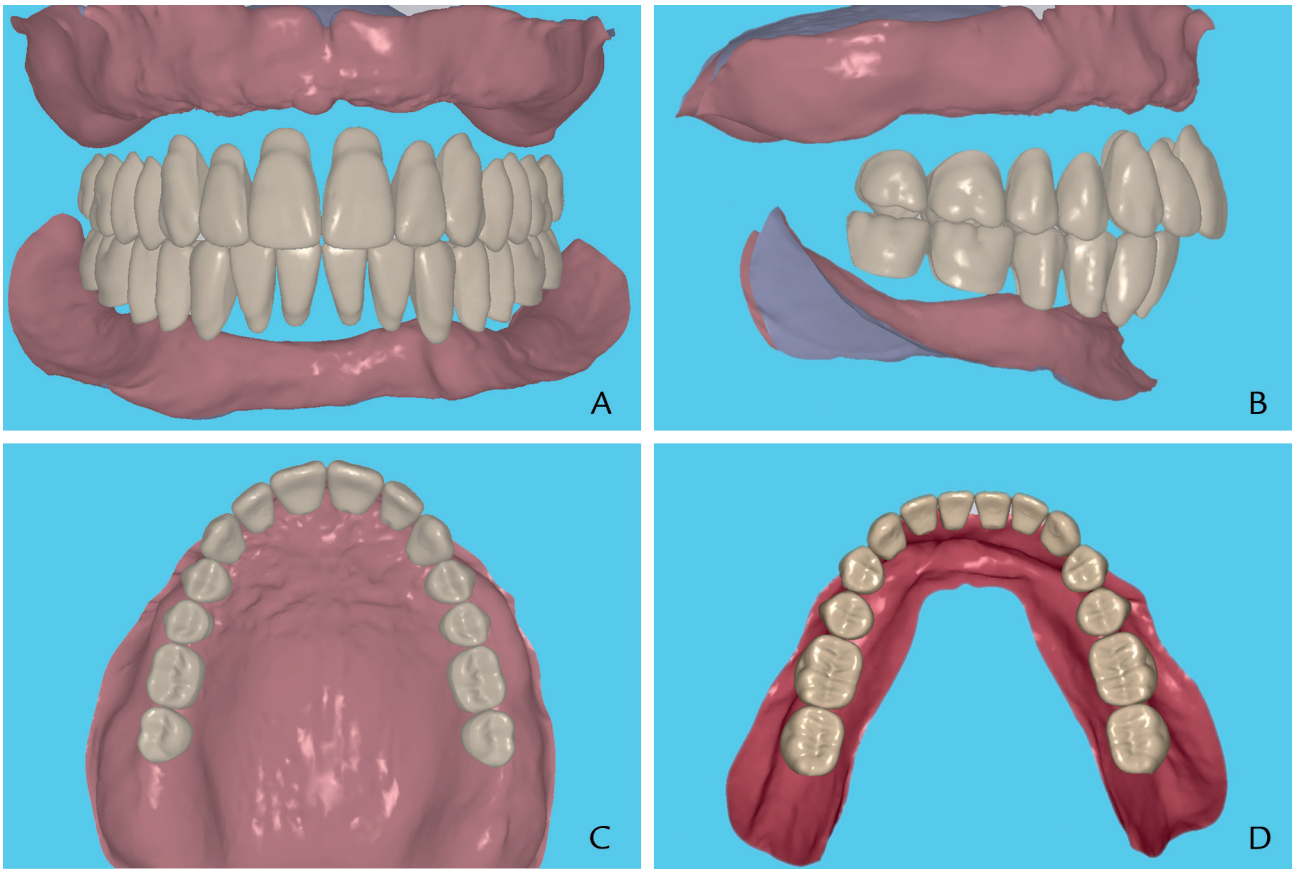

Figure 4. Digital preview images sent by manufacturer representing digital arrangement of teeth. A, Frontal view. B, Lateral view. C, Maxillary occlusal view. D, Mandibular occlusal view.

The manufacturer scanned the duplicate dentures with the impressions and all recorded clinical parameters, using proprietary laser scanning technology, thereby creating a permanent digital record. Digital tooth arrangement was then completed, and the manufacturer sent a digital preview of the arrangement by electronic mail. Each digital preview also consisted of numerous images of both arches in all 3 dimensions (Fig. 4). Any changes requested by the clinician were communicated to the laboratory technician by electronic mail, telephone, or a combination of the two until the clinician was satisfied. Monolithic dentures were then milled using a 5-axis CNC milling machine with a prepolymerized acrylic resin block and the proprietary methods of the manufacturer. A lingualized occlusion scheme (15-degree teeth) was used on all participants. The finished and polished dentures were subsequently shipped to the clinician for insertion (Fig. 5).

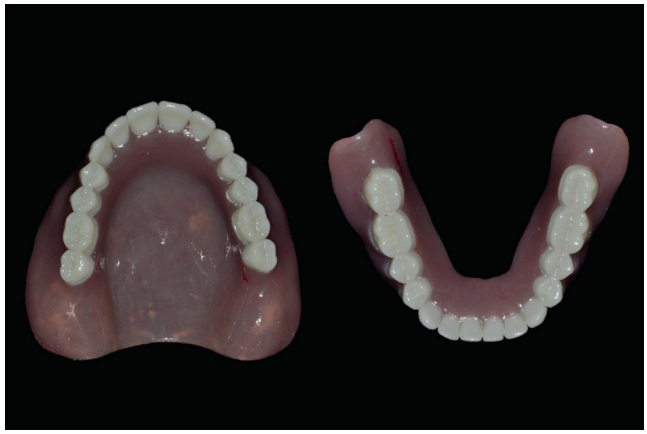

Figure 5. CAD/CAM monolithic complete dentures. CAD/CAM, computer-aided design/computer-aided manufacture.

At the second visit, the completed CAD/CAM monolithic dentures were inserted. Pressure indicator paste (PIP; Mizzy Inc) was used to indicate areas of excess pressure, which were relieved until optimal tissue contact was achieved. The occlusion was then evaluated with articulating paper, and a clinical remount procedure was performed on all 20 participants to optimize the occlusion. The adjusted dentures were replaced in the participant's mouth and standard denture care instructions were given (Fig. 6). In participants with mandibular implant-supported overdentures, the respective attachments (spherical or self-aligning) were then connected to the denture with a direct technique

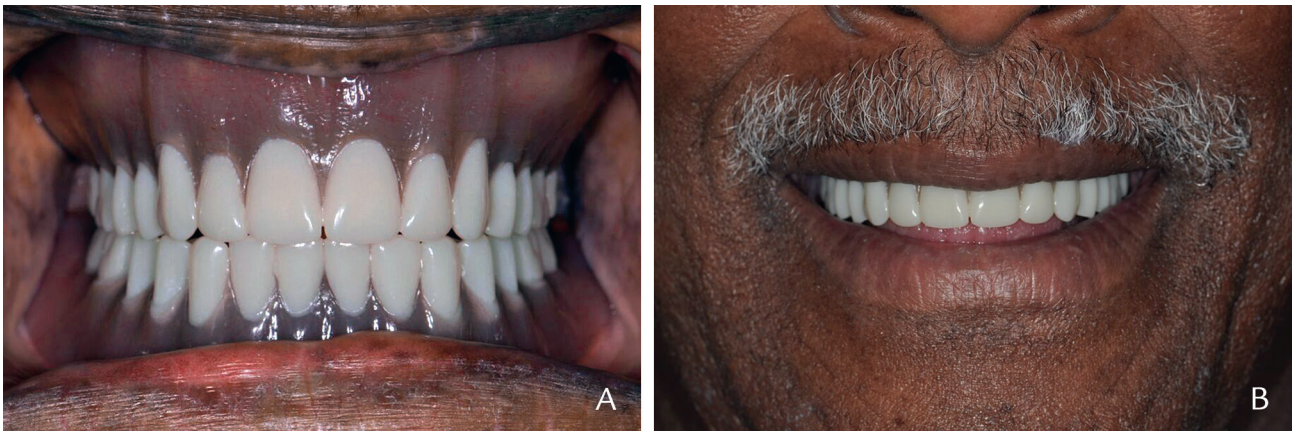

Figure 6. A, Frontal image of CAD/CAM monolithic dentures fabricated in 2 visits. B, Patient smile with CAD/CAM monolithic dentures fabricated in 2 visits. CAD/CAM, computer-aided design/computer-aided manufacture.

and a composite resin material (Quickup; Voco). At this stage, the participants submitted their existing complete dentures to avoid the possibility of not wearing the CAD/CAM dentures. The submitted dentures were to be returned to the participants after 1 year.

Follow-up appointments for all participants were performed at 1 day, 1 week, and 1 month after insertion, according to standard prosthodontic protocols. During the first month, the participants and the 2 prosthodontist judges independently completed a survey instrument using a visual analog scale (VAS) to record baseline evaluations for various patient-centered and clinical outcomes (Table 2).[18,19] The VAS instrument was presented on a printed sheet of paper with a standardized 100-mm line with a specific question pertaining to each outcome. The response to each question was indicated by a mark on the 100-mm line, which was later measured using a ruler and then recorded. For clinical outcomes, both judges evaluated each patient independently by inspection and palpation of the complete dentures and oral cavity. Thereafter, all participants were requested to return after 1 year for a follow-up examination. They were advised to return for any additional denture adjustments or any issues related to adverse events related to the CAD/CAM dentures. One year after denture insertion, the same VAS evaluations were performed by participants and the 2 judges. Once the evaluations had been recorded, the participants were informed of the conclusion of the clinical trial, and the patient's previous dentures were returned to them.

To analyze the clinical outcomes, the VAS ratings by the 2 prosthodontist judges at baseline and 1-year follow-up were calculated for median values and ranges. The change in VAS ratings from baseline to 1 year was summarized for each variable and each of the 2 judges. Finally, the consistency of the VAS scores between judge 1 and judge 2 for each variable was assessed using the Cohen kappa coefficient. To study the patient-centered outcomes, the median values and ranges of changes in the VAS ratings from baseline to 1 year were calculated. The improvements were tested by the 1-sided sign test with an exact P value (α=.05). All statistical analyses were carried out with statistical software (R3.1.2; R-Statistics).

A VAS score difference of 20 or more from baseline to 1 year was defined as clinically significant. As this was a baseline study of CAD/CAM dentures, the authors divided the VAS data into 2 sets defined as favorable (70.1-100) and unfavorable ($\leq$70) to evaluate the outcomes qualitatively and provide meaningful clinical interpretations. Favorable ratings were subdivided into excellent (90.1-100), good (80.1-90), and fair (70.1-80). Participants' dentures were considered treatment failures if the patient refused to wear the CAD/CAM dentures, withdrew from the study, or returned to their previous dentures.

RESULTS

The average age of all the participants recruited in the study was 68.4 years. Detailed demographic information for all 20 participants, along with the MM House mental classification and characteristics, is presented in Supplemental Table 1. Of 20 participants, 3 (1 exacting and 2 philosophical) were lost to follow-up, and 3 (2 hysterical and 1 exacting) were dissatisfied with the digital dentures shortly after insertion and withdrew from the study. Those 3 participants were considered treatment failures based on the study protocol, and therefore, no outcomes were recorded. All 3 participants reported that the CAD/CAM dentures were unsatisfactory with respect to esthetics, occlusion, and comfort. Their original dentures were returned to them, and they were advised to continue prosthodontic care through conventional

Table 2. Clinical and corresponding patient-centered outcomes studied[a]

Outcome No.	Clinical Outcome	Patient-Centered Outcome
1	Retention	Tightness
2	Stability	Absence of rocking
3	Extensions	Bulkiness
4	Overall esthetics	Cosmetics
5	Lip support	Lip projection
6	Occlusion	Bite/Ability to Chew
7	Speech	Ability to speak normally
8	Polish and finish (denture quality)	Finish of denture
9	Intimate adaptation of bases	Absence of food underneath denture
10	Tissue health/condition	Absence of denture sore spots
11	Overall assessment	Overall denture satisfaction
12	Appropriate occlusal vertical dimension	None
13	None	Treatment time to make the dentures

[a]Outcomes 1 through 11 were considered comparable; items 12 and 13 were noncomparable.

denture treatment. Of the 14 remaining participants, 9 had implant-retained mandibular overdentures, and 5 had conventional mandibular complete dentures.

Median ratings for clinical outcome evaluations were favorable and showed minimal differences from baseline to 1-year evaluation for both judges (Table 3). The VAS score for each participant at baseline and at 1-year follow-up remained in the same qualitative subset. The Cohen kappa coefficient between judge 1 and judge 2 indicated minimal consistency (Table 4). An average of 5 emails per participant (0-11) were sent communicating with the laboratory technicians on the CAD design of the dentures, and an average of 3.3 denture adjustments were needed after insertion (0-10) during the 1-year period (Supplemental Table 1). Additional communications by telephone were also made. All of this resulted in considerable time being spent on the communication process.

For patient-centered outcomes, the median ratings of all 14 participants indicated each of the 12 studied outcomes was favorable at the 1-year recall (Table 5). These evaluations showed minimal differences from baseline and at 1-year evaluation. Again, the VAS score for each participant at baseline and at 1-year follow-up stayed in the same qualitative subset. Statistically significant improvements in participant ratings from baseline to 1 year were observed for absence of denture sore spots and treatment time ($P<.05$). However, these differences were not clinically significant based on the predetermined difference of 20 mm used in this study. Minor complications related to loss of retention (1 participant), excessive wear of teeth (3 participants), and need for significant number of denture adjustments (1 participant) were observed. Two participants were required to visit the clinician for an additional appointment as the laboratory technician needed to verify the extreme class II maxillomandibular relationship records that were submitted. Records were reverified at the third visit and did not require any changes; therefore, the integrity of the 2-visit protocol was uncompromised.

To compare ratings for clinical and patient-centered outcomes, the proportion of excellent and good ratings for each outcome was evaluated (Table 6). The proportion was calculated by dividing the number of excellent or good ratings for each outcome by the total number of ratings (14). For patient-centered outcomes, the proportion of excellent and good ratings for each of the 12 outcomes was higher than that of the clinicians, with 79% of the patients being satisfied with their CAD/CAM dentures overall. However, approximately 50% of them did not rate good or excellent for retention ("tightness"), stability ("absence of rocking"), and adaptation of the bases ("absence of food underneath the denture"). For clinical outcomes, the proportion of excellent and good ratings for overall assessment was only 50% by the first judge and 69% by the second. No adverse clinical or patient-centered outcomes related to the CAD/CAM dentures were found and all dentures were intact and in good condition at the 1-year follow-up.

DISCUSSION

Results of this prospective cohort pilot cohort study showed that 2-visit CAD/CAM monolithic dentures fabricated using a duplicate denture protocol have favorable clinical and patient-centered outcomes. The size of the convenience sample in this clinical trial was limited to 20 participants, as this was a pilot study and designed to establish trends and guide future research. However, the loss of participants in a small sized pilot study can easily under-power a study, and this is a study limitation.

This study used 2 experienced board certified prosthodontists as judges for all clinical outcome evaluations to remove any bias in assessments by the treating clinicians and to provide independent unbiased assessments by experienced specialists. Recruiting prosthodontists as judges was an obvious choice because of their specialty, education, and expertise with complete dentures. Two judges was felt to be an adequate number to establish baseline data. The judges were not calibrated in their assessments to provide as much independence in evaluations as possible. Additionally, in a baseline pilot study, the calibration of judges who are inexperienced in evaluating CAD/CAM dentures may be counterproductive and may introduce bias in evaluations. The consistency between the 2 clinicians was evaluated in a categorical scale. Additionally, an exact test was chosen for this study to study all differences in ratings between baseline and 1-year evaluation because the sample size

Table 3. Clinical outcomes of VAS ratings (mm) at baseline and at 1-year evaluation

	Judge 1			Judge 2		
Clinical Outcome	**VAS Rating at Baseline, median (range)**	**VAS Rating at 1-y Evaluation, median (range)**	***P***	**VAS Rating at Baseline, median (range)**	**VAS Rating at 1-y Evaluation, median (range)**	***P***
Retention	94.7 (20.2-100)	75.5 (32.5-94)	.989	88.3 (47.9-97.9)	83 (38.5-100)	.806
Stability	98.4 (63.8-100)	91.8 (68-100)	.954	85.1 (54.3-96.8)	81.9 (50-100)	.387
Extensions	85.1 (44.7-97.9)	84.5 (62.8-93)	.709	87.2 (60.6-95.7)	78.7 (34-91)	.927
Overall esthetics	91.5 (62.2-96.8)	87.8 (73-100)	.291	84 (55.3-100)	82 (65-100)	.806
Lip Support	89.4 (70.2-100)	93.3 (80-100)	.133	93.6 (56.4-100)	87.2 (74.5-98)	.981
Occlusion	85.1 (51.1-93.6)	77.6 (29.8-95.7)	.709	84 (66-100)	85.1 (26.6-100)	.927
Speech	98.9 (79.8-100)	100 (91-100)	.291	78.7 (48.9-93.6)	83 (61.7-100)	.613
Polish and finish (denture quality)	86.2 (79.8-93.6)	85.1 (80-91.5)	.709	88.3 (72.9-93.6)	81.9 (69-94.1)	.927
Intimate adaptation of bases	91.5 (63.8-100)	98 (69.1-100)	.133	88.3 (60.6-94.7)	85 (52-95.7)	.981
Tissue health and condition	87.2 (70.2-100)	97.9 (71.8-100)	.046	87.2 (42.6-100)	76 (38-100)	.194
Appropriate OVD	97.3 (76.6-100)	100 (83-100)	.291	88.3 (38.3-100)	93 (52-100)	.073
Overall assessment	81.9 (62.8-96.3)	80.4 (61.7-93.6)	.500	87.2 (57.4-93.6)	85 (63-100)	.806

OVD, occlusal vertical dimension; VAS, visual analog scale.
P<.05 (using sign test) represents statistically significant differences in ratings of outcomes between baseline and 1-year evaluations.

was small. The Wilcoxon signed rank test (generally more powerful than the sign test) was not used because its exact test does not accept ties.

The duplicate denture protocol introduced by Global Dental Science was used instead of their original protocol using the manufacturer's custom trays and their proprietary anatomic measuring device (AMD). This decision was made based on the premise that the duplicate denture protocol required less experience (especially to obtain appropriate OVD and lip support) and would be used in the future by a great number of clinicians. It is unlikely that the use of the AMD method changed the conclusions of the study, as the method of digital scanning, digital previews, and milling of CAD/CAM dentures remained the same. In this study, 9 participants had implant-retained mandibular overdentures, and 5 participants had conventional mandibular complete dentures, all of which were opposing maxillary complete dentures. This is because of the characteristics of the population treated in this study. It is unlikely that the absence of implants in the mandible changed the conclusions of the study, since these participants had been wearing the implant- retained overdentures for many years before the start of the trial, and no implants were placed during the trial. Additionally, the authors did not attempt to compare the ratings of conventional denture patients with implant-retained overdenture patients given the limited sample size.

The VAS instrument was used for all evaluations in this study because it is a simple, well-validated method to quantify, record, and evaluate qualitative outcomes that are difficult to measure by direct means.[18,19] Its use was justifiable in this trial because it simulates and quantifies routine clinical evaluations performed in the dental office. An additional advantage of using the VAS method was that it allowed a comparison of clinical outcomes and patient-reported outcomes for all comparable variables. One recognized disadvantage of using the VAS instrument is that the data usually present a wide range, as seen in the results of this study. Despite this, the authors believe that the VAS instrument represents the best possible method available for quantifying clinical observations and outcomes. The authors considered using the oral health impact profile instrument (OHIP-14)[20] but chose not to, as the survey questions in OHIP-14 were unlikely to satisfy the objectives of the clinical trial. Additionally, the method of rating in the OHIP-14 incorporates zeroes, which may compromise the ability of the OHIP-14 to detect within-subject change.[21]

A monolithic CAD/CAM denture was chosen in this clinical trial over the option of bonding commercial denture teeth to the CAD/CAM milled base because it purports to offer maximum strength and durability and reduced debonding or fracture of denture teeth and

Table 4. Cohen kappa coefficient between judge 1 and judge 2 showing lack of consistency between judges' evaluations

Outcome	**Baseline (*P*)**	**1 y (*P*)**
Retention	0.39 (.01)	0.45 (.01)
Stability	0.08 (.51)	0.06 (.66)
Extensions	-0.06 (.72)	-0.15 (.3)
Overall Esthetics	-0.25 (.14)	-0.22 (.18)
Lip Support	0.08 (.62)	-0.01 (.95)
Occlusion	-0.08 (.59)	0.07 (.52)
Speech	-0.01 (.95)	0 (1)
Polish and finish (denture quality)	0.5 (.001)	0.07 (.59)
Intimate adaptation of bases	0.24 (.22)	0.18 (.16)
Tissue health/condition	0.13 (.39)	0.15 (.2)
Appropriate OVD	-0.14 (.33)	0.05 (.7)
Overall assessment	0.02 (.91)	0.05 (.74)

OVD, occlusal vertical dimension.
Consistency was significant if *P*<.05.

Table 5. Patient-centered outcomes represented by median and range of VAS ratings (mm) at baseline and 1-year evaluation

Patient-Centered Outcome	Baseline VAS Rating, median (range)	1-y VAS Rating, median (range)	*P*
Tightness	86.2 (44.7-100)	84.5 (21-100)	.709
Absence of rocking	89.4 (57.4-100)	81 (22-100)	.709
Bulkiness	89.4 (31.9-100)	91 (1-100)	.291
Cosmetics	94.7 (71.3-100)	94.8 (72.5-100)	.709
Lip projection	93.6 (63.8-100)	94.3 (27.7-100)	.500
Bite and ability to chew	90.4 (36.2-100)	91.5 (22-100)	.291
Ability to speak normally	93.6 (64.9-100)	93 (78-100)	.133
Finish of denture	93.6 (51.1-100)	94.3 (79-100)	.867
Absence of food underneath dentures	90.4 (21.3-100)	76 (11-96.8)	.709
Absence of denture sore spots	63.8 (8.5-100)	91.5 (12-100)	.046
Treatment time-make the dentures	78.7 (38.3-100)	93.5 (68.1-100)	.011
Overall denture satisfaction	85.1 (45.7-100)	92.8 (54-100)	.291

VAS, visual analog scale.
P<.05 (using sign test) represents statistically significant difference in ratings of outcomes between baseline and 1-year evaluation.

Table 6. Proportion of excellent or good VAS ratings for each outcome and raters(s) at 1-year follow-up

Outcome	Judge 1	Judge 2	Participants
Retention (tightness)	0.50	0.54	0.57
Stability (absence of rocking)	0.71	0.54	0.50
Extensions (bulkiness)	0.71	0.46	0.79
Overall esthetics (cosmetics)	0.93	0.62	0.86
Lip support (lip projection)	0.93	0.85	0.86
Occlusion (bite and ability to chew)	0.36	0.69	0.79
Speech (ability to speak normally)	1	0.54	0.86
Polish and finish of the denture	0.93	0.54	0.93
Intimate adaptation of bases (absence of food underneath the denture)	0.93	0.69	0.43
Tissue health and condition (absence of denture sore spots)	0.93	0.46	0.71
Appropriate OVD (noncomparable)	1	0.77	NA
Treatment time to make dentures (noncomparable)	NA	NA	0.86
Overall assessment (overall denture satisfaction)	0.5	0.69	0.79

NA, not applicable. OVD, occlusal vertical dimension.

represents the state of the art in complete dentures.[13] A 2-visit denture protocol was chosen over a 3-visit digital denture protocol to test this treatment protocol for maximum yield. Additionally, the manufacturer (Global Dental Science) originally marketed their product as a reliable 2-visit CAD/CAM denture. We assumed that most clinicians would be curious to know the feasibility and validity of this protocol. The authors believe that all the treatment failures and complications seen in this clinical trial would have been avoided if a trial denture placement had been performed at a third clinical visit. Although the exact time and effort spent on making a clear duplicate denture and the time required to communicate and approve the digital previews were not measured, these are comparable with the chairside time spent on conventional methods of making a conventional complete denture in 4 or 5 visits. With the arrival of digital dentistry, a trend is emerging, where even though the chairside time is reduced, considerable time (away from the chairside) is required by dentists for the planning, communication, and execution of digital dentistry procedures. Improvements in protocols and rate of learning may speed up this process in the future. Furthermore, patient ratings for treatment time were not significantly higher than for other outcomes, nor clinically significant, indicating that the use of a trial denture at a third visit may improve outcomes for CAD/CAM dentures. A large-sample randomized controlled crossover trial comparing a 4- or 5-visit conventional denture to a 2- or 3-visit CAD/CAM denture may help answer these questions.

CONCLUSIONS

Within the limitations of this prospective pilot cohort study, the following conclusions were drawn:

1. Clinical and patient-centered outcomes for CAD/CAM monolithic dentures fabricated using a 2-visit protocol were evaluated favorably at a 1-year follow-up.
2. The proportions of excellent and good ratings for overall satisfaction according to assessments were higher for patients than for clinicians: 79% of the patients were satisfied overall with their CAD/CAM dentures.
3. The clinical outcome evaluations and patient-centered outcome evaluations showed minimal differences from baseline to 1-year evaluation, with the patient-centered outcomes showing statistically significant improvement in ratings for absence of denture sore spots and treatment time to make the dentures.
4. The only clinically significant improvement (difference of VAS score of 20) between baseline and 1 year in this study was observed for absence of denture spots.
5. Two-visit CAD/CAM complete dentures are a viable treatment option for clinicians and patients, but careful patient selection and experience in the clinical and laboratory aspects of designing the CAD/CAM denture must be considered. Additional time and effort are needed to evaluate digital previews and participate in the electronic communication process with the dental laboratory technician.

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Supplemental Table 1. Demographic information, MM House mental classification, patient characteristics, and number of digital preview emails for participants. Participant numbers 7, 13, and 20 were treatment failures, and 12, 14, and 16 were lost to follow-up

Patient	Age (y)	Gender	Race	House Classification	Denture Wearing Experience (early or experienced)	Type of Existing Prostheses in Mandible*	No. of Emails Used for Digital Preview Process
1.	75	Female	White	Philosophical	Experienced	2-implant overdenture	5
2.	58	Male	White	Philosophical	Early	Complete denture	4
3.	58	Female	Other	Exacting	Early	2-implant overdenture	4
4	82	Male	White	Philosophical	Experienced	2-implant overdenture	11
5.	63	Male	White	Philosophical	Early	4-mini implant overdenture	5
6.	72	Female	White	Philosophical	Experienced	Complete denture	5
7.	73	Female	White	Hysterical	Experienced	2-implant overdenture	5
8.	83	Female	White	Philosophical	Early	2-implant overdenture	4
9.	75	Male	White	Philosophical	Experienced	2-implant overdenture	6
10.	68	Male	White	Philosophical	Experienced	2-implant overdenture	7
11.	66	Male	White	Philosophical	Experienced	Complete denture	11
12.	46	Female	Other	Hysterical	Experienced	Complete denture	1
13.	90	Male	White	Exacting	Experienced	2-implant overdenture	6
14.	61	Male	Black	Philosophical	Early	Complete denture	0
15.	62	Male	White	Exacting	Experienced	Complete denture	10
16.	53	Female	Other	Philosophical	Experienced	Complete denture	7
17.	64	Male	Black	Philosophical	Experienced	Complete denture	2
18.	70	Male	Black	Philosophical	Early	2-implant overdenture	1
19.	73	Female	White	Philosophical	Experienced	2-implant overdenture	1
20.	77	Female	White	Hysterical	Experienced	2-implant overdenture	2

*All participants had complete dentures in maxilla.