

CLINICAL RESEARCH

## Clinical performance of CAD-CAM-fabricated complete dentures: A cross-sectional study



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Complete denture (CD) rehabilitation is the most conventional prosthodontic treatment for patients with edentulism who have anatomical, psychological, or financial restraints that contradict implant therapy; however, many essential treatment variables have not been scientifically validated.<sup>1-3</sup> The methods of CD fabrication have remained relatively constant since the introduction of poly(methyl methacrylate) in 1936.<sup>4</sup> The conventional protocol for fabrication involves a complex sequence of multiple clinical and laboratory steps.<sup>5</sup> On average, this process involves at least 5 appointments, assuming the patient approves and accepts the overall esthetics at the trial insertion appointment before the CD prosthesis is processed.<sup>6</sup> This complexity may discourage clinicians from offering CD rehabilitation as part of their service. Most CD therapy is provided by general clinicians; indeed, the findings

### ABSTRACT

**Statement of problem.** Computer-aided design and computer-aided manufacture (CAD-CAM)-fabricated complete dentures (CD) seek to address the disadvantages associated with conventional CD fabrication. However, few if any randomized clinical trials, cross-sectional, and/or retrospective analyses are available for the clinical performance of CAD-CAM-fabricated CDs.

**Purpose.** The purpose of this retrospective study was to evaluate clinician experience with digital CD fabrication attempted in a 2-visit protocol. The actual number of appointments required for insertion and the number of postinsertion adjustment visits, and whether the incidence of treatment complications was related to operator experience were recorded and evaluated.

**Material and methods.** Patients who had received CAD-CAM-fabricated CDs were identified from a retrospective chart review. The number of appointments needed to insert digital CDs in attempting the 2-visit fabrication protocol marketed by the company, the number of postinsertion adjustments, and the reported complications were counted. There was no control group for comparative purposes used in this study. Whether the experience level of the operator influenced the frequency of a complication, the number of appointments needed to insert the definitive prostheses, and the number of postinsertion visits was determined by using an analysis of variance assessed at the 95% confidence level ( $\alpha=.05$ ). The frequency of a complication at each of the levels of operator experience was analyzed using the Exact Mantel-Haenszel chi-square test.

**Results.** Of the 48 rehabilitated participants, 24 participants were treated at the predoctoral level and 24 were treated at the graduate prosthodontics resident level. A total of 31 participants satisfied the true 2-visit fabrication protocol, and the remaining 17 participants required additional clinical visits because of complications on the day of insertion. The CD prostheses of 5 participants from the sample population required remaking using the conventional method. The mean number of postinsertion adjustment visits was 2.08. Of the 90 arches completed, 22 prostheses could not be inserted at the second appointment.

**Conclusions.** The mean number of appointments needed to insert the prostheses in both groups was 2.39 visits—not 2 as claimed by the company. The most common types of complications observed were lack of denture retention, inaccurate occlusal vertical dimension, and incorrect centric relation. (*J Prosthet Dent* 2016;116:431-435)

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## Clinical Implications

CAD-CAM-fabricated complete dentures may be a viable treatment option for carefully selected patients and, if the 2-visit protocol is successful, could prove cost effective. However, clinicians should be prepared for additional visits if complications arise at the insertion appointment.

of a recent study indicate that in the year 2010, in the United States alone, approximately 9 million dentures were fabricated and less than 5% were fabricated by trained prosthodontists.<sup>7</sup> Therefore, cost and time efficient CD fabrication protocols which still maintain the fundamental concepts and provide favorable outcomes for patients should be established.<sup>8,9</sup>

Computer-aided design and computer-aided manufacturing (CAD-CAM) has made significant contributions in the field of dentistry since its early introduction in the 1980s. Many reports have described the use of CAD-CAM technology for fabricating fixed, removable, and implant-supported prostheses.<sup>10</sup> CAD-CAM-fabricated implant-supported prostheses, single, multiple, or complete arch, have been widely used and documented. However, few reports have described the application of CAD-CAM technology to the fabrication of conventional CDs.<sup>11,12</sup>

A method of fabricating CDs with CAD-CAM technology which may simplify and shorten patient visits has been described.<sup>13</sup> According to Bidra et al,<sup>14</sup> one of the most important advantages of this type of technology is the fabrication of CDs in only 2 clinical appointments. Definitive impressions, maxillomandibular records, and tooth selection are completed in the first appointment, reducing both chairside and laboratory work and saving time.<sup>14</sup> Even though some may consider this treatment controversial because of the unconventional nature of the technique, Bidra et al<sup>14</sup> suggested that CAD-CAM-fabricated CDs can positively influence patient care, dental curricula, and research.

One of the most significant advantages of the digital CD fabrication system claimed by its manufacturer is the reduction in the number of appointments and the reduction in clinical chair time over the conventional protocols of CD fabrication.<sup>12</sup> However, long-term clinical data are lacking regarding the true outcome of these CD prostheses. The purpose of this retrospective study was to evaluate predoctoral (PRED) and postgraduate (GRPR) student performance by using CAD-CAM CD system and relate experience level to the number of appointments for insertion and postinsertion adjustment visits<sup>15</sup> and to evaluate whether the incidence of treatment complications was related to operator experience.<sup>16</sup>

## MATERIAL AND METHODS

This study evaluated patients treated between the 2012 and 2014 and received approval by The Ohio State University's Biomedical Sciences Institutional Review Board (protocol no. 2014H0024) in November 2014. Inclusion criteria included edentulous individuals who were seeking prosthodontic treatment in The Ohio State University College of Dentistry Clinics and who had received treatment using AvaDent digital denture system (Global Dental Science LLC). Patients requiring immediate digital CDs, however, were excluded. With the assistance of a dental software search tool (Windent EE; Carestream Dental), this cross-sectional study collected data from the charts of patients rehabilitated with digital CDs and treated in the predoctoral comprehensive care clinics and the advanced prosthodontics clinic. The study sample included 48 participants, 23 women and 25 men, ranging from 26 to 90 years of age, and a mean of 62.79 years of age. A data collection template was developed to facilitate and standardize the gathering of data from the participant's clinical charts. Collected chart data were evaluated for objective treatment outcomes, including the total number of appointments needed to insert the definitive maxillary and mandibular CDs, the total number of postinsertion adjustment visits, and any reported complications. Data were collected by a single examiner (P.S.) to avoid interexaminer variability. Participants' age and sex were recorded, and each participant was assigned a study identification number in accordance with federal Health Insurance Portability and Accountability Act (HIPAA) regulations. The number of postinsertion adjustment visits and number of appointments needed to insert the removable CD prostheses were recorded for each participant.<sup>17,18</sup> If more than 2 appointments were needed to insert the prostheses, the reasons were identified and recorded. The data collection template also included the most common CD complications, and the incidence of these complications was recorded. Furthermore, the complications the patients presented were associated with the level of clinician experience (PRED and GRPR) to evaluate whether a relationship existed.

For each level of operator experience, the mean, standard deviation and 95% confidence levels about the mean were determined for the number of appointments needed to insert the definitive prostheses and for the number of postinsertion visits. Whether the experience level of the operator influenced the number of appointments needed to insert the definitive prostheses and the total number of complications observed was then determined using an analysis of variance (PROC MIXED, SAS v9.3 software; SAS Institute Inc) ( $\alpha=.05$ ). The frequency of a complication in each of the levels of operator experience was analyzed with the exact Mantel-Haenszel

**Table 1.** Appointments needed to insert CDs in each group

Appointment	Total, n	PRED, n	GRPR, n	Total, n
2		16	15	31
3		8	8	16
5		0	1	1
Total, n		24	24	48
Mean ±SD		2.33 ±0.481	2.45 ±0.721	2.39 ±0.085

CD, complete dentures; GRPR, graduate prosthodontics; PRED, predoctoral.

chi-square test using software (PROC FREQ with EXACT statement, SAS v9.3; SAS Institute Inc).

**RESULTS**

Of the 48 rehabilitated participants, 24 participants were treated at the PRED level and 24 at the GRPR resident level. A total of 90 digitally fabricated CD prostheses were inserted: 47 maxillary CDs, 34 mandibular CDs, and 9 implant-supported mandibular overdentures. All complete mandibular overdentures were retained by 2 endosteal dental implants and a locator attachment system. The mean number of appointments needed to insert the prostheses at the PRED level was 2.33 (95% CI: 2.13-2.53) and 2.45 (95% CI: 2.15-2.76) at the PRGR resident level. The mean number of appointments required for both the PRED and GRPR groups was 2.39 compared with the 2 appointments claimed to be necessary by the company (Table 1). The reasons more than 2 appointments were required to insert the prostheses were noted and recorded (Table 2).

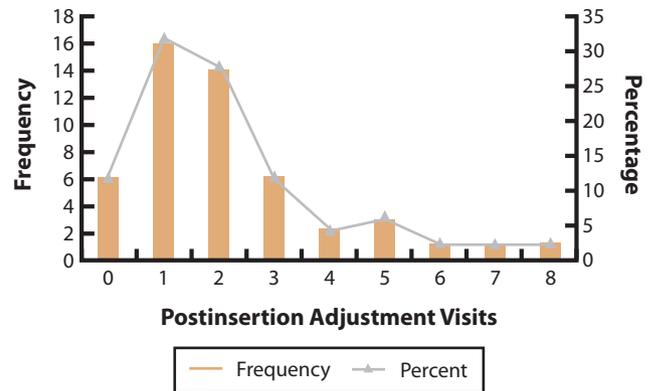
Participants treated at the PRED level required an average of 2.12 postinsertion adjustment visits (95% CI: 1.34-2.90), and participants treated at the GRPR resident level required a mean of 2.04 clinical visits (95% CI: 1.26-2.81). The mean number of postinsertion adjustment visits for the sample population was 2.08 due to the presence of ulcers or “sore spots”; 33% of the participants treated required 1 post adjustment visit, followed by 29% of the participants requiring 2 visits and 12% requiring no adjustment at all (Fig. 1). Of the 90 arches completed, 22 could not be inserted at the second appointment. For this, the reasons most commonly reported were lack of denture retention (8 of 22 participants), incorrect occlusal vertical dimension (4 of 22 participants), incorrect CR (3 of 22 participants), and unacceptable esthetics (3 of 22 participants). One reported complication was altered speech.

All 22 dentures not inserted at the second appointment were inserted at the third appointment. Of the 48 participants in this study, a total of 17 participants required more than 2 clinical appointments to insert the definitive prostheses. Fourteen participants presented complications on the day of insertion and required additional appointments. The other 2 participants had an esthetic clinical evaluation appointment, requested by the operator, which increased the number of total

**Table 2.** Reasons CDs were not inserted in 2 clinical visits for 17 participants who presented with more than 1 complication

Reasons for Insertion in >2 Appointments	Frequency, n	Percent
Esthetics off	3	13.63
Phonetics off	1	4.54
Lack of retention	8	36.36
Incorrect occlusal vertical dimension	4	18.18
Incorrect centric relation	3	13.63
Operator requested wax evaluation denture	2	9.09
Fracture at overdenture locator interface	1	4.54

CD, complete dentures.



**Figure 1.** Postinsertion adjustment visits for study population.

appointments. A total of 4 participants presented with more than 1 complication. The frequency of common complications in terms of total number of arches completed is identified in Table 3.

Results of the exact Mantel-Haenszel chi-square test showed no statistical differences regarding operator experience in terms of the number of appointments needed to insert the digital CD prostheses ( $P=.474$ ). No statistically significant differences were noted for the number of postinsertion adjustment visits between both groups ( $P=.873$ ). Two thirds of all participants had no complications; the remaining one-third presented with 1 or more complications, and no differences were found for the occurrence of complications between dental students and residents. ( $P=.062$ ).

**DISCUSSION**

The mean number of appointments needed to insert CAD-CAM-fabricated CD prostheses in both the PRED and GRPR groups was 2.39. Also, no statistically significant differences were found between operator experience and the number of appointments required to insert the dentures ( $P=.474$ ). The number of participants treated in the advanced prosthodontics clinic and PRED comprehensive care clinics were identical. Having faculty supervising and guiding the operators with the technical steps could have influenced the similar mean number of appointments needed to insert the prostheses at both levels of operator experience.

**Table 3.** Frequency and percentage of participants with complications

Complication	Frequency, n	Percent
Laboratory processed relines	6	37.50
Remakes to conventional CDs	5	31.25
Soft denture relines	2	12.50
Repair of fractured OVD	1	6.25
Hard relines of palate to improve speech	1	6.25
Possible allergic reaction to material	1	6.25

CD, complete dentures; OVD, overdenture.

One of the most significant advantages of CAD-CAM-fabricated CDs involves the recording and transferring of clinical information in 2 clinical visits to produce high quality, high performance prostheses that re-establish the patient's function, esthetics, and phonetics. Compared with conventional CD fabrication, which involves at least 5 clinical visits, the findings suggest a considerable reduction in the total number of appointments needed. This finding is clinically significant as clinicians can offer more cost efficient treatment methods. Patient satisfaction was also measured by means of a survey, and the participants reported being generally pleased and satisfied with this their overall treatment outcome and experience.<sup>8</sup> This, in turn, may indicate that, regardless of operator training and expertise, this method of CD fabrication can be predictable as long as prosthodontic fundamentals are applied.

A similar number of complications were observed at both the PRED and the GRPR level. This fact could be attributed to the learning curve associated with this relatively new method of CD fabrication. However, the PRED students did receive a certain degree of training and exposure to this system through the use of teaching materials and observation of the clinical steps involved with another student or faculty member before attempting the 2-visit technique. In this way, efforts were made by the clinical faculty to calibrate the students before they used this system for their patients with edentulism. Conversely, the GRPR students were only given an overview presentation of the system by the company's marketing representative and were encouraged to familiarize themselves with the steps and appropriate materials in order to attempt the 2-visit protocol with the guidance of attending faculty. Therefore, the reason that no difference in experience levels was found may have been that all students and residents were, in fact, guided and coached by the faculty, potentially making conclusions on comparative outcomes meaningless. However, the faculty to PRED student ratio was generally 1 to 6 for a given clinic session, making it virtually impossible for the faculty to coach every step on a one-to-one basis. Also, although the methods of registering CR are taught in PRED curriculums, the centric bearing tracing is rarely used in educational institution clinics. It could also be hypothesized that both

groups are in a learning institution trying to improve their prosthodontic clinical experience.

The most frequently encountered significant complications were the lack of denture retention on the day of denture insertion (8 of 22 participants) followed by increased occlusal vertical dimension (4 of 22 participants); these findings are in accordance with other results from a previous study.<sup>16</sup> These clinical problems were overcome with laboratory processed functional relines (37.50%) and the placement of soft, interim denture liners (12.50%). The high prevalence of lack of retention on the day of insertion may have been influenced by improperly made edentulous definitive impressions. Both dental students and graduate students are taught different edentulous definitive impression techniques (functional and nonfunctional impression techniques), and this, along with operator inexperience, could have influenced the overall quality of the definitive impression sent to the company for scanning and consequent milling of the denture bases. In addition, the company claims that the fit of the dentures is better than that of a conventionally fabricated denture base because of the method of processing the acrylic resin for the denture base.<sup>1</sup> Although a posterior palatal seal is not required because there is no polymerization shrinkage of the acrylic resin, it may be requested in the prescription order. The absence of a posterior palatal seal and an inaccurate definitive impression could also have influenced the retention of the prostheses on the day of insertion.

In this study, the patients who received CDs with inaccurate occlusal vertical dimension (increased) and incorrect CR required clinical remount procedures and/or redesigning and remilling of the prostheses. Two of the 5 participants required the prostheses to be remade with the conventional method as the occlusal vertical dimension was excessive.

The esthetic concerns identified as a complication involved deviated maxillary midlines and excessive gingival display. One participant developed a suspected allergic reaction, characterized by epithelium sloughing, to the digital prosthesis, which was remade in the conventional way. Once the conventionally fabricated CDs were inserted for this participant, the signs and symptoms subsided. The remaining 2 participants had had extractions performed less than 2 months before the definitive impressions were made to begin the digital denture fabrication. The entries from these participants' charts described inadequate denture retention on the day of prosthesis insertion and the provision of soft temporary relines with tissue conditioning materials (Lynal tissue conditioner and temporary reliner kit; Dentsply Caulk). Eventually, both participants required new prostheses fabricated in the conventional way. Research shows that complete socket calcification occurs between 8 and 12 months after tooth extractions and that the bone volume

of the ridge is reduced by 20% to 30% in the first year.<sup>5</sup> Because a 2-month healing time could be considered insufficient, the digital CD fabrication method cannot be held responsible for producing ill-fitting prostheses as traditional postextraction guidelines were not initially followed.

Several studies have reported that patients have positive perceptions of CD therapy.<sup>2</sup> Drago<sup>15</sup> determined that postinsertion denture adjustments for conventional CD patients are a multifactorial and complex phenomenon. In his retrospective clinical study, the average number of adjustment visits was 2.86 for patients treated with a traditional and modified impression technique in CD therapy. In this present study, the mean number of postinsertion adjustment visits for the sample size was considered less than the previous findings at 2.08. Another study found similar numbers of postinsertion adjustment recall visits.<sup>6</sup> Eighty-seven percent of those treated (42 of 48 participants) required at least 1 postinsertion adjustment visit. These findings are similar to the results of Kivovics et al<sup>17</sup> and Sadr et al,<sup>18</sup> in which 85.8% and 87% of participants respectively required adjustments in the 24 hours after insertion. One study found a correlation between the number of postinsertion adjustments and patient satisfaction levels; the lower the number of recall visits, the higher the scores obtained for patient satisfaction.<sup>9</sup>

This study has some limitations. Ideally, a comparative trial with a conventional CD group would have been conducted to render true clinical outcomes. This, in turn, could have led to a true randomized trial providing the highest level of evidence. The retrospective chart portion of this study had its limitations, such as omitted information, subjective clinical documentation, and the length of the time for data collection. Updated clinical chart notes could have been added if scheduled follow-up chart reviews had been performed after collection of the original data.

Even though the conventional technique of CD fabrication has been clinically predictable for over 100 years,<sup>3</sup> clinical and laboratory research is needed to mitigate the disadvantages. Once the disadvantages associated with the current design software and programs are overcome, CD fabrication could be commercially manufactured by medical informatics instead of dental technicians.<sup>10</sup> Prospective and standardized clinical studies involving more patients requiring CAD-CAM CDs are needed to improve patient care and to provide evidence-based research that addresses treatment outcomes. Further research is needed with substantial sample sizes and longer follow-up periods to validate the performance of this treatment alternative.<sup>14</sup> There is a pressing need to improve dental education with regard to CDs by incorporating digital technology without disregarding the fundamentals.<sup>14</sup>

## CONCLUSIONS

The mean number of appointments needed to insert CAD-CAM-fabricated CDs was 2.39 and the number of postinsertion appointments was 2.08 for both groups. No apparent differences in the number of appointments required to insert CAD-CAM-fabricated CDs ( $P=.474$ ), number of postinsertion adjustment visits ( $P=.873$ ), and incidence of complications were observed between PRED and postgraduate students ( $P=.062$ ).

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