THE JOURNAL OF PROSTHETIC DENTISTRY

CLINICAL RESEARCH

# Clinical evaluation of laboratory-made and CAD-CAM–fabricated occlusal devices to treat oral parafunction

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## ABSTRACT

**Statement of problem.** The demand for occlusal devices to treat oral parafunction is rising. Conventionally, these occlusal devices are produced in the dental laboratory, which requires impressions and gypsum casts. Computer-aided design and computer-aided manufacturing (CAD-CAM) require fewer production steps and may offer greater comfort. Whether this is an improvement on conventional procedures is unclear.

**Purpose.** The purpose of this crossover clinical study was to examine whether a digital workflow is feasible for fabricating occlusal devices to treat oral parafunction and to compare CAD-CAM–fabricated occlusal devices with conventionally produced ones to determine whether the digital method provides better results.

**Material and methods.** Thirty participants wore digitally fabricated occlusal devices for 3 months and then conventionally produced occlusal devices for another 3 months or vice versa. The main target parameter was the participant's preference for 1 of the device types.

**Results.** Both types had specific advantages and disadvantages, but the differences in participants' preference were not statistically significant. After completing the 2 testing periods, 16 participants preferred the laboratory-made device, whereas 12 participants preferred the digital occlusal device. Two participants dropped out during the study.

**Conclusions.** Given the absence of statistically significant differences, the digitally fabricated device can be considered a suitable alternative to laboratory-made devices. Laboratory-made occlusal devices are now the gold standard. However, given the savings in terms of cost and treatment time, they may be replaced, particularly if the production process can be improved. (J Prosthet Dent 2019;122:123-8)

Bruxism rates have been reported to be 15%[1] and 20%[2] in adults. The condition describes parafunctional clenching and grinding of the maxillary and mandibular dentition[3] during the day or at night.[4] Occlusal discrepancies, stress, certain medications, and the intake of caffeine and nicotine have been cited as potential causes.[3,5,6] Possible consequences include increased tooth and restoration wear,[7,8] periodontal damage, and myofascial trigger pain or craniomandibular dysfunction.[9,10] These conditions are often treated by using occlusal devices, using evidence-based treatment adjuncts that protect the teeth, decreasing muscle tone,[11-13] improving jaw-opening capacity,[14] and reducing head or neck pain and craniomandibular symptoms.[15]

Conventional occlusal devices fabricated in the dental laboratory require time-consuming chairside impressions and laboratory steps (fabrication of a gypsum cast and the occlusal device itself and adjustment of the occlusal table). Because many patients are prescribed these devices, it would seem appropriate to reexamine and reconsider the conventional manufacturing method.

Innovations in the computer-aided design and computer-aided manufacturing (CAD-CAM) technology have enabled the elimination of design and treatment steps. Automated CAD-CAM production has reduced treatment cost[16,17] and eliminated possible sources of error.[18] In addition, the digital scanning technique has been described as more effective.[19] Kuhr et al[20] compared the accuracy of conventional complete-arch impressions

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## Clinical Implications

A digital workflow for producing occlusal devices for oral parafunction therapy can be recommended. In addition, the digital scanning technique greatly enhanced participants' comfort and is therefore well suited even for patients with an exaggerated gag reflex.

using a polyether impression material with the results obtained from 3 intraoral scanners. Superimposition of the different mandibular complete-arch scans yielded deviations of 37 ±14 μm for the cara TRIOS (Kulzer GmbH) scanner, a value not significantly different from that for True Definition (3M ESPE) scanner. However, the conventional impression still exhibited the smallest deviation at 15 ±4 μm.

Patients have been reported to prefer intraoral scanning to conventional impressions.[19,21-23] The present crossover study examined the feasibility of using CAD-CAM technology to produce occlusal devices and compared the digital manufacturing process with the conventional workflow. The research hypothesis was that occlusal devices fabricated using the digital manufacturing process would be equivalent to those fabricated using the conventional workflow.

## MATERIAL AND METHODS

Approval for the study was obtained from the Ethics Committee of Johann Wolfgang Goethe University of Frankfurt. Thirty participants who satisfied the following inclusion criteria participated in the study: presence of parafunctional activity (bruxism); only natural dentition or fixed prostheses; and agreement to participate in the study. Participants had to be 18 years or older, with no more than 1 missing tooth per quadrant. Exclusion criteria were a history of psychosomatic disease; addiction to alcohol, drugs, or analgesics; pregnancy; malignant disease; acute events such as trauma or inflammation; bisphosphonate therapy within the last 5 years; removable dental prostheses; known hypersensitivity to materials; and extensive temporomandibular disorder.

The sample size of the study was based on the study by Heydecke et al,[24] which also focused on participants' satisfaction and final decisions. For the present study, 30 participants, who received detailed information, were randomly assigned to 2 equal groups. The participants received a sealed envelope, which contained a number for randomization into 2 groups (odd number=group CD and even number=group DC). Evaluation used the crossover method, and a standard functional analysis was carried out before each treatment.

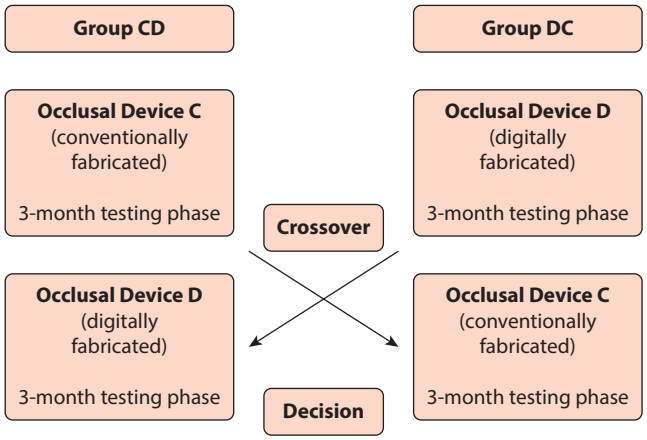


**Figure 1.** Study design.

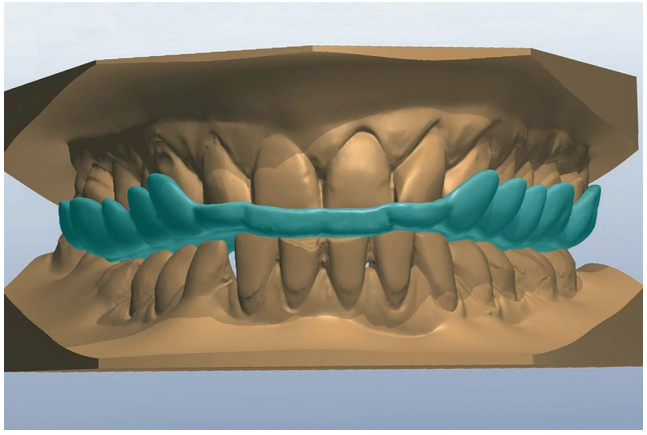

**Figure 2.** Completed design of occlusal device.

Participants in both groups received 2 occlusal devices prepared using different techniques to be worn at night for a test period of 3 months. Each participant received both types of occlusal device, but the order within the groups was reversed. Thus, participants in group CD first received the conventionally made occlusal device (device C), whereas those in group DC first received the digitally fabricated occlusal device (device D). In the second testing phase, participants in group CD received the digitally fabricated device and those in group DC received the conventionally fabricated device (Fig. 1).

To make the occlusal devices comparable despite the different production methods, standardized fabrication guidelines were established. At the time of the study, arbitrary facebow transfers and centric relation records were not available in the digital workflow. Both occlusal devices were therefore fabricated in the maximum intercuspal position and after central placement of the definitive casts (digital and conventional) in the articulator.

Both the digital and conventional workflows permitted adjustments to the static occlusion in the digital or physical articulator. The digital articulator did not, however, allow dynamic movements, so the

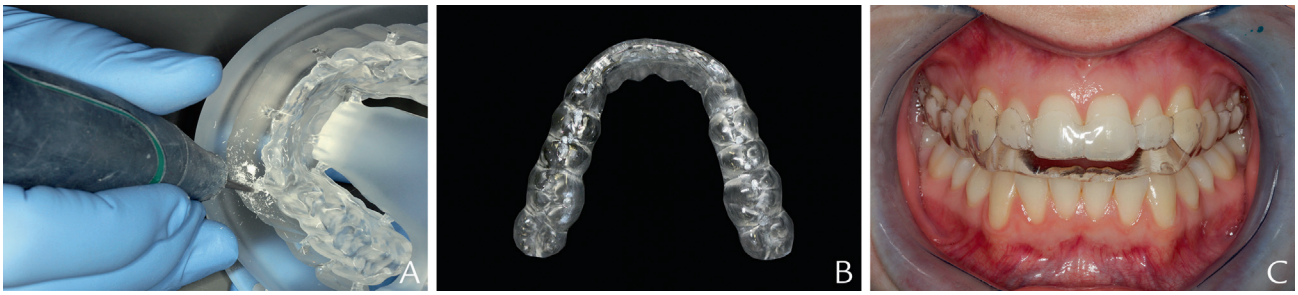


**Figure 3.** Device D. A, Blank after milling and separation. B, After polishing. C, After chairside occlusal adjustment. D, digitally fabricated occlusal device.

extraoral adjustment of devices C and D was based on the static occlusion. The dynamic occlusion (anterior/canine guidance) was adjusted intraorally for both occlusal devices to establish the baseline situation. The virtual and conventional articulators had the same adjustments (horizontal inclination of condylar guidance, 40 degrees; Bennett angle, 25 degrees).

Device C was produced conventionally by making an impression (Impregum Penta; 3M ESPE) and recording the maximum intercuspal position. The maxillomandibular relationship was recorded in wax, with the record trimmed to obtain the correct position of the cast. This record extended only to the first molar to keep the vertical dimension increase to a minimum. The casts (hydro-stone 180; dentona AG) were mounted in a semiadjustable articulator (SAM 2P; SAM Präzisionstechnik GmbH), and the devices were fabricated from prosthetic resin (Eclipse; Dentsply Sirona).

Production followed a standardized protocol with a minimum intermaxillary thickness of 1 mm and a buccal extension to 1 mm below the survey line. The device was photopolymerized and finished, and only the static occlusion was adjusted on the articulator.

Device D was produced by a digital process by using an intraoral scanner (cara TRIOS; Heraeus Holding GmbH). After scanning the maxilla and mandible, participants were instructed to close in the maximum intercuspal position. This occlusal relationship was recorded with a buccal scan to improve the matching of the digital casts. The digital data were processed by using a CAD-CAM software program (Ortho System; 3Shape A/S). The software's Appliance Designer module was used to mount the digital models in the virtual articulator by using semiadjustable parameters (condylar inclination and Bennett angle). The occlusal device was produced according to the protocol for the conventional variant (Fig. 2).

The device was milled in a milling unit (CORiTEC 450i; imes-icore GmbH) from a clear plastic blank (PMMA milling blank; Yamahachi Dental Mfg, Co) following a predefined milling protocol that provided for an exchange of the milling cutters at specific intervals. The device was then separated from the blank, polished, and adjusted intraorally (Fig. 3).

**Table 1.** Data acquisition: participants

| Parameter | 0% | 100% |
|---|---|---|
| Influence of size and volume of occlusal device | Nonexistent | Existent |
| Encroachment on mouth and tongue space | | |
| Changes in fit | | |
| Changes in retention | | |
| Handling | Easy | Difficult |
| Familiarization period | Short | Long |
| Occlusion | Interferences | No interferences |
| Wearing comfort | Unpleasant | Pleasant |
| Impression technique | | |

Data were collected at delivery and at 3 months. Standardized questionnaires produced values for specified parameters from the participant's and the operator's perspective. Data acquisition generally used visual analog scales (VASs) 10 cm in length and representing percentages from 0 to 100, whose interpretation differed depending on the parameter examined (Table 1). The main target parameter was the participant's final decision (yes/no) in favor of device C or device D.

The operator (A.K.) evaluated the occlusal contacts with 8-μm shimstock (Hanel Shimstock Foil; dental bauer) and made yes or no decisions. The number of antagonistic contacts was reported as a percentage. In addition, the stability of the devices was reported as a yes/no decision, with 4 options defined (0=rigid; 0.5=very low mobility; 1=some mobility; and 2=pronounced mobility). Results were made comparable by averaging. Subsidiary target parameters were also evaluated using VASs (Table 2).

The VAS data acquired were analyzed statistically using the Koch crossover test and the Wilcoxon-Mann-Whitney-U-Test. Yes/no decisions were analyzed using binomial distributions ($\alpha$=.05 for both tests). The Koch crossover test also examined possible carryover effects for parameters. Any carryover effects were described and excluded from further analysis. The evaluations were performed using a statistical software program (BiAS v10; epsilon Verlag).

## RESULTS

The participants (19 women and 11 men) were aged between 22 and 33 years (mean: 24.9 years). The

**Table 2.** Data acquisition: operators

| Parameter | 0% | 100% |
|---|---|---|
| Support | Nonexistent | Existent |
| Fit | Excellent | Bad |
| Extent of occlusal adjustments | None | Extensive |

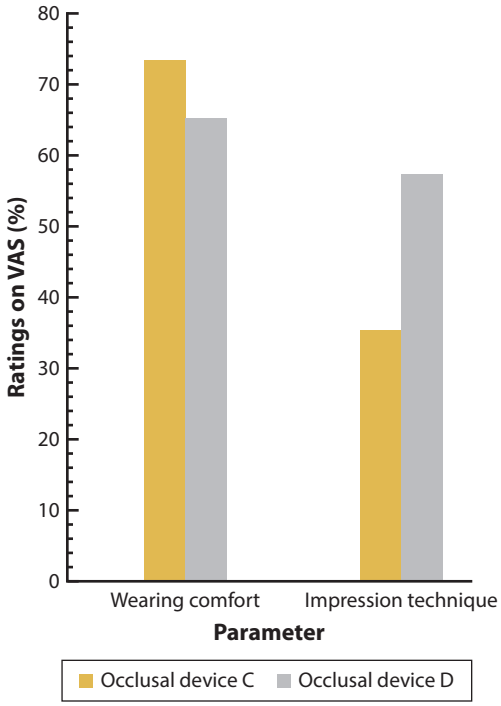


**Figure 4.** Wearing comfort and impression technique. C, conventionally made occlusal device; D, digitally fabricated occlusal device; VAS, visual analog scale.

following results are based mainly on the Wilcoxon-Mann-Whitney-U-Test results of the first testing period as some parameters exhibited aftereffects that made the evaluation for the second testing period unusable. Furthermore, 2 participants dropped out during the second testing phase. However, the crossover design ensured that the second testing period was not neglected as its data were used for the Koch crossover test.

The impression technique parameter was rated significantly better for the intraoral scans ($P$=.004) in the Koch crossover test for participant evaluations. On the VASs, conventional impressions received a mean rating of 35.2%, whereas intraoral scanning received a mean rating of 57.3% (Table 1). The devices were not significantly different for wearing comfort ($P$=.235) (Fig. 4).

The final choices favored device C in 16 instances and device D in 12 instances, which translates into an effect in the binomial distribution of 57.1% ($P$=.572) (Table 3). The ratings for other secondary target parameters are displayed in Figure 5.

**Table 3.** Overview of groups and sequences of occlusal devices

| Participant Number | First Occlusal Device | Second Occlusal Device | Final Decision |
|---|---|---|---|
| 1 | C | D | C |
| 2 | C | D | C |
| 3 | C | D | D |
| 4 | C | D | C |
| 5 | C | D | D |
| 6 | C | D | D |
| 7 | C | D | C |
| 8 | C | D | C |
| 9 | C | D | C |
| 10 | C | D | D |
| 11 | C | D | D |
| 12 | C | D | D |
| 13 | C | D | D |
| 14 | C | D | C |
| 15 | C | D | D |
| 16 | D | C | C |
| 17 | D | C | C |
| 18 | D | C | C |
| 19 | D | C | C |
| 20 | D | C | D |
| 21 | D | C | C |
| 22 | D | C | Dropout |
| 23 | D | C | D |
| 24 | D | C | D |
| 25 | D | C | Dropout |
| 26 | D | C | C |
| 27 | D | C | C |
| 28 | D | C | C |
| 29 | D | C | D |
| 30 | D | C | C |

C, conventionally made occlusal device; D, digitally fabricated occlusal device.

The operators' evaluation of antagonistic contact points shows a slightly higher incidence of missing interocclusal contacts at the beginning of the first testing phase than at the initial delivery at 67.7% for device C and 65.5% for device D.

Stability changed as shown in Figure 6. The time required for adjustment of the occlusal table was rated as 58.9% for device C and 42.2% for device D ($P$=.07, Wilcoxon-Mann-Whitney-U-Test). Device C was rated more highly in terms of retention than device D. The initial fit was rated as 38.5% for device C and 41% for device D (Fig. 7).

## DISCUSSION

The collected data within the scope of the present prospective study support the research hypothesis. Furthermore, the participants' evaluations indicated that intraoral scanning was preferred to conventional impressions ($P$=.004).

To make the occlusal devices broadly comparable despite their different fabrication methods, the

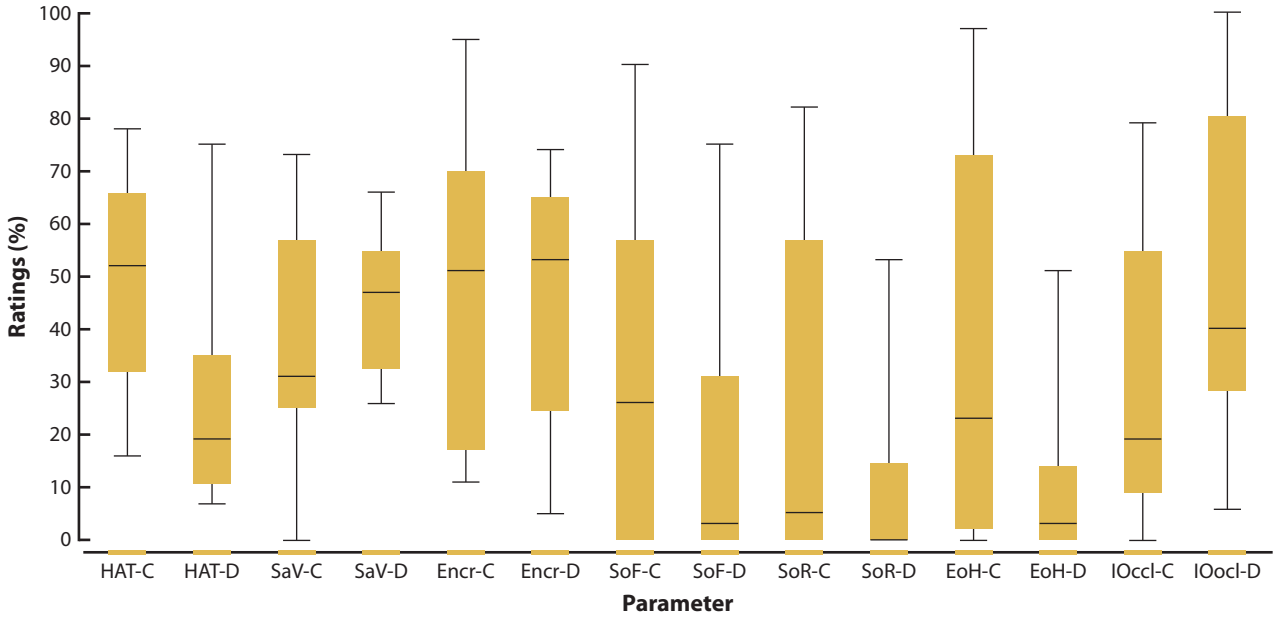


**Figure 5.** Secondary target parameters of devices C and D. C, conventionally made occlusal device; D, digitally fabricated occlusal device; Encr, encroachment on mouth and tongue; EoH, ease of handling; HAT, habituation time; IOccl, initial occlusion; SaV, size and volume; SoF, stability of fit; SoR, stability of retention.

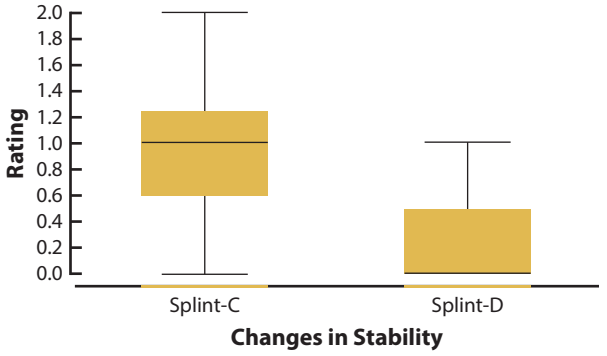


**Figure 6.** Changes in stability.

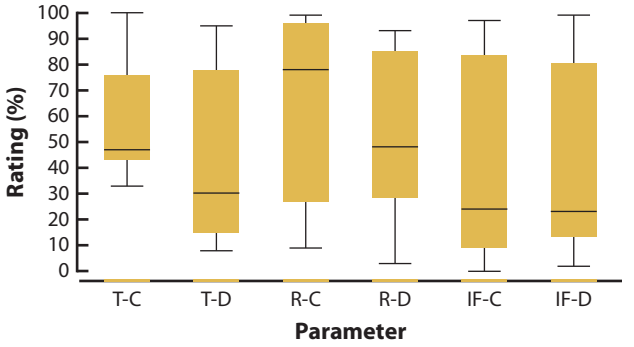


**Figure 7.** Ratings of devices C and D from operator's perspective. C, conventionally made occlusal device; D, digitally fabricated occlusal device; IF, initial fit; R, retention; T, time required for adjustment.

production processes were fine-tuned to be as similar as possible. The devices were made in maximum intercuspal position and generally showed balanced results, without statistically significant differences. The materials used to produce the devices were similar but not identical. However, after a wearing time of only 3 months, the expected wear was low and therefore can be neglected, as can the difference in materials.

For ethical reasons, no washout period was used between the testing phases because participants suffered from oral parafunction and a washout period would have meant no treatment and may have intensified symptoms. Nevertheless, the study design and statistical tests helped reduce bias and possible carryover effects for each parameter examined.

The participants' ratings showed that the size and volume of device C were perceived as favorable at first delivery. The better ratings for encroachment on mouth and tongue space after the first test phase were consistent with these assessments.

The wearing comfort ratings at the end of both testing phases were slightly better for device C, which had also been described as offering a high level of wearing comfort by Leib.[25] The final decisions of 16 participants in favor of device C and those of 12 in favor of device D showed no significance in the binomial distribution. By contrast, ratings for habituation time were in favor of device D. Although significant differences between devices C and D were absent, the superiority of device D in terms of handling at insertion and removal may have had a positive influence on habituation time. Furthermore, the ratings for

device D at the end of the first 3 months indicated a higher stability of fit and retention, with lower wear on the devices with Eclipse than with other materials.[26] This was not consistent with the ratings in the present study. However, other factors such as the regularity with which the devices were worn were not examined in the present study.

In the Koch crossover test, the intraoral scan was rated as significantly more comfortable than the conventional impression ($P$=.004). This finding is consistent with those of other studies and confirms that participants typically prefer digital scans over conventional impressions.[19,21-23]

Yuzbasioglu et al[19] reported that the intraoral scanning technique was more effective, requires fewer steps, reduces the number of necessary materials, and eliminates possible sources of error while improving the occlusal fit of the finished device. This was confirmed by better ratings for device D with respect to the initial occlusal situation, from both the participant's and the operator's perspective. The overall absence of statistical significance may be related to the sample size. Calculations were based on minimum relevant differences of 40 points on the VASs.[24] However, evaluations in this study also showed differences below this threshold.

Based on these initial results, the authors believe that digitally fabricated occlusal devices may replace conventional laboratory-made devices even in situations where an exact adjustment of the occlusal table is required. The digital production method can be recommended as an alternative approach in the treatment of parafunction such as bruxism.

## CONCLUSIONS

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

1. Digitally fabricated occlusal devices are a viable alternative to conventional laboratory-made occlusal devices in the treatment of oral parafunction.

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https://doi.org/10.1016/j.prosdent.2018.11.017