

# Double-blind comparison between optical and conventional impressions for the production of mandibular advancement devices

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## Abstract

**(1) Background: Obstructive sleep apnea syndrome (OSAS) is a sleep disorder with a high social and health impact. Mandibular advancement devices (MADs) are considered a viable treatment option and a possible first-line treatment in this setting. No study in the literature has investigated clinical aspects of these devices in relation to the procedures**

**used to manufacture them. The aim of this study was to compare the clinical adequacy of MADs produced starting from conventional analog versus digital impressions; (2) Methods: Four patients were recruited. For each of them, two MADs were produced: one starting from an intraoral scan and the other from the digitalization of a plaster model based on analog impressions. Clinical parameters of the two devices were evaluated and compared; (3) Results: No statistically significant differences in the clinical parameters evaluated were found between the two groups of devices; (4) Conclusion: Optical and conventional impressions show similar accuracy in the production of MADs.**

**Keywords:** digital dentistry; sleep medicine; mandibular advancement device

## Introduction

Obstructive sleep apnea syndrome (OSAS) is a sleep disorder characterized by partial or complete obstruction of the upper airway during sleep, leading to disrupted breathing patterns [1,2]. It is relatively common, affecting approximately 2-4% of adults in the general population. While OSAS can occur at any age, it is more prevalent in middle-aged males [3]. Several risk factors contribute to the development of this condition, including obesity (BMI > 30), upper airway obstructions such as nasal turbinate hypertrophy, septum deviations or nasal polyps, tobacco and alcohol consumption, and the presence of craniofacial anomalies like maxillary hypoplasia or micrognathia. The consequences of OSAS are significant, impacting various aspects of an individual's life. Daytime sleepiness, impaired vigilance, and cognitive dysfunction are common symptoms that affect a person's ability to perform daily activities effectively. These symptoms also contribute to an increased risk of motor vehicle accidents, occupational injuries, and a lower overall quality of life [4]. The diagnosis should be based on the patient's medical history and on a clinical and instrumental examination. Questionnaires like the Epworth Sleepiness Scale, Berlin questionnaire, and STOP-Bang questionnaire are used to guide the clinical assessment. The most accurate diagnostic examination for OSAS is polysomnography, which is performed in a sleep laboratory. Polysomnography involves continuous nocturnal recordings, including measurements of various parameters such as electroencephalogram, electrooculogram, electromyography, nasal and oral airflow, respiratory effort, oxygen saturation, body position, and electrocardiogram. Moreover, considerable evidence

suggests that OSAS is independently associated with cardiovascular disease, cerebrovascular disease, and type 2 diabetes [5,6]. Thus, early diagnosis and effective management of OSAS are crucial for reducing the risk of these comorbidities. Continuous positive airway pressure (CPAP) is the treatment of choice for mild, moderate, and severe OSAS, and should be offered as an option to all patients. Alternative therapies may also be proposed depending on the severity of the OSAS and the patient's anatomy, risk factors, and preferences [7]. In recent years, oral appliances (OAs) have emerged as a popular alternative treatment for OSAS and snoring [8]. OAs, specifically mandibular advancement devices (MADs), are recommended for patients with mild to moderate OSAS who prefer them over CPAP or who do not respond well to CPAP [7]. MADs cover the upper and lower teeth, holding the mandible in an advanced position, typically forward by 5 to 11 mm (50-75% of maximal protrusion) [4], to improve the patency of the upper airway during sleep by enlarging it and/or by decreasing its collapsibility. Anterior movement of the tongue or mandible can increase the cross-sectional airway size and may also improve upper airway muscle tone [9].

Traditionally, the production of oral devices involved conventional impression taking and manual construction of the appliance. However, with advancements in computer technology and dental processing, a fully digital workflow based on CAD/CAM (Computer-Aided Design/Computer-Aided Manufacturing) technology has become feasible [10]. Intraoral scanners (IOS) have become widely available and offer an efficient and accurate alternative to conventional impressions. Numerous studies have reported that current intraoral scanners demonstrate clinically valuable accuracy, at least comparable to conventional impression-based approaches.

Whereas *in vivo* studies report that full-arch impressions are associated with distortion phenomena, for single-tooth restorations or fixed partial prostheses of up to 4-5 elements, the scientific literature deems the accuracy of optical impressions to be satisfactory and similar to conventional impressions. However, for more extensive restorations such as partial fixed prostheses with more than 5 elements or full-arch prostheses on teeth or implants, intraoral scanning might not offer the same level of precision as conventional impressions [11,12]. Regarding orthodontic purposes, digital models appear to be as reliable as traditional plaster models, and full-arch impressions obtained using IOS can replace traditional ones [13-15]. Although the precision of these complete-arch scans is currently considered inferior to that obtained using conventional impressions, reports also show that IOS is sufficiently accurate for the fabrication of occlusal devices, such as Michigan splints, in a fully digital workflow [16,17].

Currently, no study in the literature evaluates the use of optical impressions in the production of MADs used in OSAS treatment, and overall, no study has investigated aspects such as the accuracy, fit and comfort of MADs in relation to device manufacturing procedures. The aim of this study is to assess the clinical accuracy of MADs produced using CAD/CAM technology with two different impression techniques: conventional impression taking and intraoral scanning. By comparing the two approaches, researchers hope to shed light on the potential benefits and limitations of using digital impressions in the production of MADs for patients with OSAS.

## Materials and Methods

In this research study, the focus was on evaluating the clinical parameters of mandibular advancement devices (MADs) produced using two different impression techniques: intraoral scans and digitalization of traditional plaster models. The aim was to identify which of these two methods might offer the best accuracy for MAD fabrication. During the experimental phase, both the intraoral scan and traditional plaster model techniques were utilized to produce the MADs for each volunteer. These devices were then thoroughly evaluated based on several critical clinical parameters. The ease of insertion and removal of the MADs was assessed to determine how user-friendly and manageable they were for the volunteers. Adequacy of shape and margins examined the precision and accuracy of the devices in fitting the individual's dental anatomy. Retention, another crucial parameter, gauged how well the MADs stayed in place during use, ensuring optimal effectiveness during sleep. Comfort, a significant aspect, was evaluated to ascertain the overall satisfaction and tolerance of the participants with each MAD, aiming to identify the technique that provided a more comfortable fit. To achieve this, four healthy volunteers were recruited as participants from among the patients attending a private dental office (Table 1).

**Table 1.** Patients recruited for the study

|           | Sex  | Age |
|-----------|------|-----|
| Patient 1 | Male | 40  |
| Patient 2 | Male | 40  |
| Patient 3 | Male | 36  |
| Patient 4 | Male | 30  |

The patients selected were all healthy adult men with good oral health. Patients with contraindications to oral devices, such as periodontal disease, dental mobility, poor tooth retention, inadequate temporomandibular joint range of motion, or extensive tooth loss, were excluded from the study. All volunteers had lost no more than one tooth, excluding third molars, during their lifetime, making them ideal candidates for the research.

In this study, two impressions of both dental arches were taken from each patient to compare the effectiveness of conventional and digital impression techniques.

The first set of impressions was obtained using a conventional technique. Monophasic impressions were taken using a polyvinyl siloxane material and standard impression trays were utilized to capture the dental arches' detailed morphology. The conventional method involves carefully inserting the tray into the patient's mouth and allowing the impression material to set and capture the teeth and surrounding structures accurately.

The second set of impressions was obtained using a state-of-the-art digital impression system. The CEREC Omnicam® intraoral scanner with CEREC Ortho SW 1.2® software (Dentsply Sirona; North Carolina, USA) was employed for this purpose. The intraoral scanner is a handheld device equipped with advanced optical technology that allows for the non-invasive capture of the dental arches in a three-dimensional digital format, providing real-time visualization and accurate digital models

of the patient's teeth and surrounding oral structures. During the acquisition of both conventional and digital impressions, the intermaxillary relationship was recorded in maximum intercuspation. Furthermore, to ensure optimal fit and function of the MADs, the patient's maximal mandibular protrusion was carefully recorded. This measurement considered the distance from the upper right central incisor to the lower right central incisor during mandibular protrusion movement, according to the oral devices manufacturer's indications.

Once the conventional and digital impressions of the patients' dental arches were obtained, two Narval CCTM dental devices (Resmed Inc., California, USA) were produced for each patient using computer-aided design/computer-aided manufacturing (CAD/CAM) techniques. The Narval CCTM devices are bi-block MADs made from semi-rigid, biocompatible polymer plastic materials. For the devices produced from the traditional impressions, a skilled dental technician transformed the impressions into plaster models. These plaster models were then scanned to create accurate digital models. These digital models served as the basis for designing the mandibular advancement devices through CAD/CAM processes. To ensure unbiased evaluation, a double-blind procedure was employed for the testing phase. An expert dental clinician with specialized training in dental sleep medicine, who was unaware of the type of MAD being used, delivered and evaluated the two devices for each patient. Additionally, the patients themselves were unaware of the type of device they were testing. To maintain anonymity during the evaluation process, a second operator assigned a unique code to each test device. This coding system ensured that the evaluator and patients could not determine which MAD was conventional and which was digital. After receiving the MADs, the volunteers were instructed to wear them for several nights during sleep. They were then asked to provide feedback on their experience, particularly regarding the level of comfort achieved and any unexpected events they encountered while using the devices.

The devices consisted of two parts, i.e., an upper and a lower splint, interconnected by exchangeable rods of different lengths. Although five design variations were available covering a range of patient needs and anatomical constraints, only one was selected for this study ("facial band" for both the upper and the lower jaw), to ensure that the devices were comparable. However, in accordance with the manufacturer's indications and based on the clinical evaluations, one patient was given different designs due to his particular dental morphology ("incisors full coverage" for both the upper and the lower jaw for the digital device; "incisors full coverage" for the lower jaw and "facial band" for the upper jaw for the analogic device).

The amount of mandibular advancement was set at 60% of maximum protrusion for all the patients. The devices were fabricated using CAD/CAM technology starting from the scanned plaster casts and optical impressions of the dental arches. Computer-aided design (CAD) enables high degree of customization to suit the complex dental anatomy of each patient. A virtual articulator was used in this stage. Computer-aided manufacturing (CAM) using selective laser sintering of a biocompatible polymer material (polyamide) guarantees consistent, industrial-strength manufacturing. In this study, the Cerec Omnicam® intraoral scanner with Cerec Ortho SW 1.2®

software (Dentsply Sirona; North Carolina, USA) was used for the acquisition of full-arch digital impressions. A full-arch guided scanning procedure was used, requiring the operator to wield the intraoral scanner throughout the process. The scanner is powder-free and relies on the principle of optical triangulation with video sequencing using white LED for image acquisition. All digital scanning procedures were performed by the same expert operator. Using Cerec Omnicam® with the Cerec Ortho® software, a 3D digital model is generated and available directly after imaging, and the integrated model analysis tools allow quick access to the clinical information. The scan data were later exported as STL digital files and sent to the laboratory in this format, attached to the order form, through the Narval Easy online portal. In order to compare the MADs produced starting from the two different impression techniques, a list of clinical parameters was drawn up to be used to test the quality of the devices.

The literature was searched to identify objective clinical parameters able to define the clinical fit of oral appliances, but poor results were found. In fact, most of the published studies concern fixed prostheses or use in vitro measurements to evaluate device accuracy. Only a few studies suggested clinical parameters that may be used to evaluate the accuracy of oral devices, such as orthodontic appliances or occlusal devices [17-21]. No study that included evaluation of the clinical accuracy of MADs was found. Supplementing the articles found in the literature, a list of parameters was established, with univocal definitions. Numerical scores were provided for each parameter based on objective criteria. Table 2 shows the list of parameters and scores.

Statistical analysis was carried out by means of paired t-test to compare the scores obtained using the different devices for the five parameters considered (insertion, removal, adequacy of margins and shape, retention, and comfort). The aim of the statistical analysis was to report differences between the scores obtained by the two groups of devices for each parameter analyzed. A comprehensive assessment of each device was also carried out, considering the total score obtained by summing the parameter scores. The comprehensive score was compared between the devices using the same statistical analysis method.

## Results

Tables 3 and 4 show the single parameter scores obtained by each device, as well as the total score for each device.

None of the devices were found during the clinical evaluation to cause side effects (such as gum soreness or crushing), and none of the patients reported side effects or discomfort after wearing them for a few nights.

Paired t-tests were carried out to test for statistically significant differences between the two groups of devices for both total scores and single parameters (Figure 1). The tests were performed using a 95% confidence level (definition of statistical significance:  $p < 0.05$ ).

## Discussion

The aim of this study was to evaluate the clinical accuracy of MADs produced both from digital and traditional impressions. The effectiveness of the devices for the

**Table 2.** Parameters and scores

| CLINICAL PAREMETER                   | SCORE                                                                                                                                                                              |                                                                                                                                                          |                                                                                                                         |
|--------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------|
|                                      | 0 (low)                                                                                                                                                                            | 1 (acceptable)                                                                                                                                           | 2 (optimum)                                                                                                             |
| <b>Insertion</b>                     | It is not possible to obtain complete insertion and the proper positioning of the device                                                                                           | The device can be placed with difficulty, or it is necessary to apply high or too little pressure, or it is necessary to make adjustments on the device. | The device can be easily placed, with no need for adjustments (snap fit)                                                |
| <b>Removal</b>                       | Difficulties occur in removing the device / the patient cannot remove the device independently                                                                                     | The device can be easily removed from oral cavity but only after adjustments                                                                             | The device can be easily removed by the patient with no need for adjustments                                            |
| <b>Adequacy of margins and shape</b> | Inaccuracies or areas of excessive pressure on tissues are found, or the patient reports discomfort wearing the device as a consequence of excessive pressure on the teeth or gums | Mild inaccuracies are found, or the device can be worn without discomfort after adjustments                                                              | Perfect congruence between shape/margins of the device and patient's tissues                                            |
| <b>Retention</b>                     | Retention of the device is lacking in both the upper and lower jaws during mouth opening and closing                                                                               | The device dislocates either the upper or the lower jaw during mouth opening and closing                                                                 | The retention of the device is sufficient to allow usual oral functions (such as swallowing, mouth opening and closing) |
| <b>Comfort</b>                       | The patient struggles with the device and cannot get used to it                                                                                                                    | The patient feels slight discomfort when wearing the device but bears it                                                                                 | The patient feels comfortable wearing the device                                                                        |

**Table 3.** Scores obtained from clinical examination of the devices

| Parameter                     | Patient 1 |         | Patient 2 |         | Patient 3 |         | Patient 4 |         |
|-------------------------------|-----------|---------|-----------|---------|-----------|---------|-----------|---------|
|                               | Analog    | Digital | Analog    | Digital | Analog    | Digital | Analog    | Digital |
| Insertion                     | 2         | 2       | 2         | 1       | 1         | 2       | 1         | 2       |
| Removal                       | 2         | 2       | 2         | 1       | 1         | 2       | 1         | 2       |
| Adequacy of margins and shape | 2         | 2       | 1         | 1       | 2         | 1       | 2         | 2       |
| Retention                     | 1         | 2       | 2         | 2       | 1         | 2       | 1         | 2       |
| Comfort                       | 2         | 2       | 1         | 0       | 2         | 1       | 2         | 2       |

treatment of OSAS was not evaluated, although considerable evidence exists supporting the effectiveness of MADs in this setting.

In the existing literature, no studies have specifically investigated aspects such as accuracy, fit, and comfort of mandibular advancement devices in relation to device manufacturing procedures. These aspects hold significant importance in clinical practice, as poorly fitting de-

vices could lead to wastage of time and resources for both dental clinics and laboratories. Moreover, ill-fitting devices may negatively impact patient comfort and compliance, ultimately affecting the overall effectiveness of the treatment.

Traditionally, the MAD production process involves taking impressions using alginate or elastomeric materials. However, advancements in technology now enable spe-

**Table 4.** Total of the scores and arithmetical means obtained by the two different groups of devices

| Parameter                                    | Total  |         | Arithmetic mean |         |
|----------------------------------------------|--------|---------|-----------------|---------|
|                                              | Analog | Digital | Analog          | Digital |
| Insertion                                    | 6      | 7       | 1.5             | 1.75    |
| Removal                                      | 6      | 7       | 1.5             | 1.75    |
| Adequacy of margins and shape                | 7      | 6       | 1.75            | 1.5     |
| Retention                                    | 5      | 8       | 1.25            | 2       |
| Comfort                                      | 7      | 5       | 1.75            | 1.25    |
| TOTAL SCORE<br>(objective parameters)        | 24     | 28      |                 |         |
| TOTAL SCORE<br>(including patient's comfort) | 31     | 33      |                 |         |

cialized laboratories to work directly from digital scans of dental arches. In modern clinical practice, full-arch scans are not only used for MAD fabrication but also for orthodontic purposes, such as diagnosis and production of orthodontic appliances. While some studies have examined the accuracy of intraoral scans, they have primarily been laboratory-based and focused on *in vitro* measurements. Only a few studies have conducted clinical assessments on the accuracy of oral appliances produced from full-arch scans, specifically orthodontic appliances or occlusal devices, and no such study has evaluated MADs. Therefore, the current study's contribution lies in its development of a comprehensive set of clinical parameters used to assess the fit of intraoral appliances and facilitate comparisons between different devices. The parameters established were supplemented with a scoring system and provided with detailed definitions, in order to make them objective and unambiguous. Furthermore, the devices were clinically tested using a double-blind procedure, to avoid conditioning of any kind. One of the essential achievements of this study was the production of two different MADs for each patient—one based on an optical scan and the other from a traditional impression. This comparative approach allowed for a comprehensive evaluation, considering potential anatomical variations between patients. It is crucial to assess how these differences might affect the clinical fit and retention of the MADs. By making these direct comparisons, the study aimed to provide more robust evidence for the clinical use of intraoral scanners in MAD fabrication.

The primary limitation of the present study is the relatively small number of patients included in the research, which affects the statistical power and generalizability of the results. However, the study has laid the groundwork for future investigations, and the aspects examined herein could serve as a basis for more extensive and robust statistical analyses in subsequent studies with larger patient cohorts.

Despite the limitations, the current study demonstrates that the use of an intraoral scanner can provide ade-

quate accuracy for producing mandibular advancement devices (MADs). This finding suggests that intraoral scanners may be a viable and reliable option for clinical practice, potentially enhancing the available evidence in the field of dental sleep medicine. However, it should be noted that the cost of producing two devices per patient, as required for the study's design, makes this approach more suitable for scientific research purposes rather than routine clinical practice. Nevertheless, some valuable conclusions can still be drawn from the present study. First, all the tested devices exhibited at least an acceptable level of accuracy, with none of the devices considered inadequate in any parameter. While one device based on an optical impression received a negative patient comfort evaluation, this aspect is subjective, and the other parameters were deemed more meaningful. Overall, both impression techniques produced satisfactory results, suggesting that they can be considered suitable for clinical practice.

Upon comparing the two groups of devices, no statistically significant differences were found in the comprehensive evaluation (total score) or individual parameters. This indicates that the accuracy of the MADs fabricated from optical impressions was similar to those made from conventional impressions.

Furthermore, it is worth noting that all the devices produced from optical impressions received the maximum score for retention. This finding is particularly noteworthy because retention is a critical aspect of MADs. Poor retention can lead to discomfort for patients and compromise the overall effectiveness of the treatment. The ability of the devices from optical impressions to achieve maximum scores for retention suggests their general high-quality construction and potential clinical utility. A deficiency in parameters such as comfort or adequacy of margins can often be rectified through chairside adjustments, whereas poor retention is a trickier problem to solve, suggesting poor general quality of the device. Insufficient retention can, in some cases, even make it necessary to remake the device.

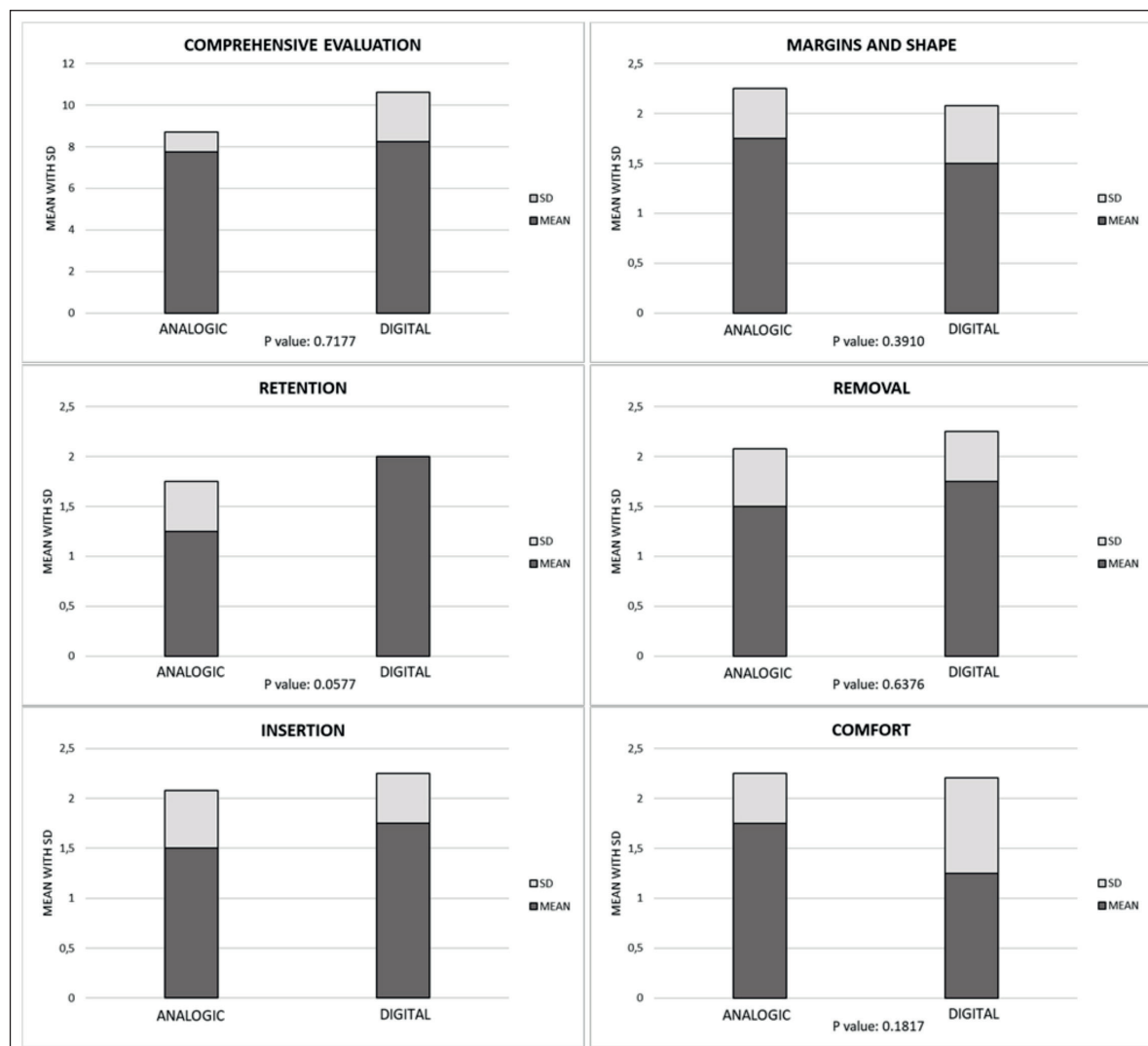


Figure 1.

## Conclusions

The findings of the current study indicate that mandibular advancement devices (MADs) produced using CAD/CAM techniques, whether starting from optical digital impressions or conventional polyvinyl-siloxane impressions, demonstrate comparable clinical fit and accuracy. These results suggest that a fully digital workflow can be effectively utilized for MAD fabrication in clinical practice, offering the possibility of obtaining high-quality devices with excellent clinical fit, similar to those produced from conventional impressions.

The adoption of CAD/CAM technology in MAD fabrication has shown promising outcomes, providing a more streamlined and efficient approach to device production. The digital workflow allows for precise customization and better adaptation to the individual patient's dental anatomy, potentially leading to improved patient comfort and treatment efficacy. Additionally, the digital process reduces the reliance on physical materials and manual labor, contributing to cost savings and shorter turnaround times for device delivery.

While the study's results are encouraging, it is essential

to acknowledge the need for further research involving larger patient cohorts. Expanding the sample size and including a more diverse patient population would help establish more statistically significant conclusions. Conducting multicenter studies with standardized protocols could also enhance the reliability and generalizability of the findings.

Incorporating additional outcome measures could provide a comprehensive assessment of the MADs' performance and patient satisfaction. Long-term follow-ups to evaluate treatment efficacy, adherence, and potential side effects would offer valuable insights into the devices' overall clinical effectiveness.

Furthermore, exploring the cost-effectiveness of the digital workflow compared to traditional methods would be beneficial for healthcare providers and patients alike. Understanding the economic implications could potentially lead to more widespread adoption of CAD/CAM techniques in dental sleep medicine.

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