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Technological diversity, manufacturing methods, and designs of mandibular advancement devices for the treatment of obstructive sleep apnea: a systematic review

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ADMINISTRATIVE INFORMATION

Support - DGAPA UNAM, PAPIIME PE208426.**Review Stage at time of this submission** - Risk of bias assessment.**Conflicts of interest** - None declared.**INPLASY registration number:** INPLASY2026100005**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 1 October 2026 and was last updated on 1 October 2026.

INTRODUCTION

Review question / Objective To systematically evaluate the technological characteristics, manufacturing methods, and design features of mandibular advancement devices (MADs) used for the treatment of obstructive sleep apnea (OSA), and to examine their association with clinical effectiveness, treatment adherence, usability, patient comfort, and treatment-related outcomes.

Review question: Among adults with obstructive sleep apnea, how are the technological characteristics, manufacturing methods, and design features of custom-made mandibular advancement devices associated with clinical effectiveness, treatment adherence, usability, and patient-related outcomes?

Rationale Mandibular advancement devices (MADs) are an established therapeutic option for obstructive sleep apnea (OSA), particularly in patients who are intolerant of or prefer an

alternative to continuous positive airway pressure. In recent years, substantial technological developments have been introduced in MAD design and manufacturing, including digital workflows, computer-aided design and manufacturing (CAD/CAM), additive manufacturing, adjustable and titratable designs, and sensor-based monitoring. However, considerable heterogeneity exists among device designs, manufacturing techniques, materials, adjustment mechanisms, and monitoring approaches, making it difficult to determine how these technological characteristics relate to clinical effectiveness and patient-centered outcomes. This systematic review therefore aims to synthesize the available evidence on the technological and design characteristics of MADs and examine their relationship with clinical effectiveness, adherence, usability, comfort, tolerability, and other treatment-related outcomes.

Condition being studied Obstructive sleep apnea (OSA) is a sleep-related breathing disorder characterized by recurrent episodes of partial or

complete upper-airway obstruction during sleep. This review focuses on adults with diagnosed OSA treated with mandibular advancement devices (MADs), with particular emphasis on the technological characteristics, design features, manufacturing methods, adjustability, and monitoring capabilities of these devices.

METHODS

Search strategy A systematic literature search was conducted in PubMed/MEDLINE, Scopus, and Dentistry & Oral Sciences Source. The search combined terms related to: (1) obstructive sleep apnea and sleep-disordered breathing; (2) mandibular advancement devices and oral appliance therapy; and (3) device technology, design, manufacturing, customization, digital workflows, additive manufacturing, sensors, and physiological parameters.

PubMed/MEDLINE: (("mandibular advancement device*" OR "oral appliance*") AND ("obstructive sleep apnea" OR OSA)) AND ("3D printing" OR CAD OR sensor* OR nanosensor* OR biometric*) NOT review[pt].

Dentistry & Oral Sciences Source: TX (("mandibular advancement device*" OR "oral appliance*") AND ("obstructive sleep apnea" OR OSA) AND ("3D printing" OR CAD OR sensor* OR nanosensor* OR biometric*)) NOT PT Review.

An initial Scopus search used combinations of the terms "MAD", "fabrication", "3D", and "apnea". An updated Scopus search was conducted on April 14, 2026 using a broader TITLE-ABS-KEY strategy incorporating terms related to OSA, mandibular advancement devices, design, technology, fabrication, CAD-CAM, 3D printing, additive manufacturing, sensors, oxygen saturation, airflow, and respiratory parameters, limited to publications from 2021 through 2026.

Participant or population Adults (≥ 18 years) with a confirmed diagnosis of obstructive sleep apnea (OSA), irrespective of disease severity, treated with a mandibular advancement device (MAD).

Intervention Custom mandibular advancement devices (MADs) used for the treatment of obstructive sleep apnea, including devices with different designs, materials, adjustment or titration mechanisms, conventional or digital manufacturing methods, CAD/CAM workflows, additive manufacturing/3D printing, and adherence-monitoring technologies.

Comparator Comparators included alternative MAD designs or manufacturing methods, conventionally manufactured MADs, active

treatments such as continuous positive airway pressure (CPAP), or baseline/pre-treatment values. A concurrent comparator was not mandatory because single-group pre-post, cohort, and clinical report designs were eligible when relevant to the technological characterization of MADs.

Study designs to be included Randomized controlled trials, non-randomized comparative intervention studies, prospective or retrospective cohort studies, quasi-experimental pre-post studies, and clinical reports. Clinical reports were included only for technological characterization and not to support comparative conclusions regarding clinical effectiveness.

Eligibility criteria Original studies and clinical reports involving adults (≥ 18 years) with confirmed OSA of any severity were eligible when they evaluated custom MADs manufactured using conventional and/or digital techniques, including different designs, adjustment mechanisms, manufacturing methods, or monitoring technologies, and reported at least one relevant clinical, adherence, usability, tolerability, or technological outcome. Reviews, meta-analyses, editorials, letters, protocols, expert opinions without original data, studies exclusively involving participants < 18 years, studies without confirmed OSA, studies evaluating treatments other than MADs, duplicate publications, and reports without sufficient methodological or outcome information were excluded.

Information sources PubMed/MEDLINE, Scopus, and Dentistry & Oral Sciences Source were searched. The initial searches were conducted on October 28, 2025, and an updated and expanded search was conducted in Scopus on April 14, 2026. Records identified through the initial and updated searches underwent the same eligibility assessment process.

Main outcome(s) The primary outcomes were the apnea-hypopnea index (AHI) and oxygenation-related outcomes, including minimum and/or mean peripheral oxygen saturation (SpO_2) and oxygen desaturation index (ODI). Outcomes were assessed at the follow-up time points reported by each included study. Because of substantial clinical and methodological heterogeneity across devices, study designs, follow-up periods, and outcome assessment methods, results were synthesized descriptively rather than pooled quantitatively.

Additional outcome(s) Secondary outcomes included daytime sleepiness, treatment adherence

(objective or self-reported), usability, patient comfort and satisfaction, tolerability, adverse effects, treatment success, and other relevant patient-reported outcomes. Technological outcomes included MAD design, materials, manufacturing method, use of CAD/CAM or additive manufacturing, adjustability/titration mechanisms, digital workflows, and integration of adherence-monitoring technologies.

Data management Records identified through the database searches were screened sequentially by title and abstract and subsequently by full text. Duplicate records were removed before screening. Three independent reviewers (VGSY, ZMAR, and TRZD) assessed eligibility according to predefined inclusion and exclusion criteria, with disagreements resolved by consensus. Data were extracted in a standardized manner, including study design, population characteristics, MAD design and characteristics, manufacturing method, comparator, follow-up duration, clinical outcomes, adherence, usability, comfort/tolerability, and adverse effects when available.

Quality assessment / Risk of bias analysis Risk of bias and methodological quality were independently assessed by three reviewers (VGSY, ZMAR, and TRZD) using design-specific tools. The Cochrane Risk of Bias 2 (RoB 2) tool was used for randomized controlled trials, ROBINS-I (Risk Of Bias In Non-randomized Studies - of Interventions) for non-randomized comparative intervention studies, and the corresponding Joanna Briggs Institute (JBI) critical appraisal tools for cohort studies, quasi-experimental studies, and clinical reports. Disagreements were resolved by consensus. Results were reported by study and domain without generating a numerical overall quality score. Certainty of evidence for the main comparative outcomes was assessed using GRADE, considering risk of bias, inconsistency, indirectness, imprecision, and publication bias.

Strategy of data synthesis A narrative and descriptive synthesis was performed because substantial clinical and methodological heterogeneity across the included studies precluded an appropriate quantitative meta-analysis. Studies were characterized according to sample size, study design, MAD configuration, manufacturing method, adjustability, follow-up duration, clinical outcomes, adherence, and patient-reported outcomes. Findings were compared across conventional and digital manufacturing approaches, device designs and adjustment mechanisms, and monitoring technologies when appropriate. Comparative

evidence for the main outcomes was additionally summarized using the GRADE framework. No pooled effect estimate was calculated.

Subgroup analysis No formal subgroup analysis was performed because of the limited number of studies and substantial heterogeneity in study designs, MAD technologies, comparators, outcome measures, and follow-up periods. Findings were descriptively examined according to manufacturing approach, device design, adjustability, and technological characteristics when appropriate.

Sensitivity analysis No formal sensitivity analysis was performed because a quantitative meta-analysis was not conducted. The influence of methodological limitations was considered through design-specific risk-of-bias assessment and the GRADE evaluation of certainty of evidence.

Language restriction Only articles published in English were included.

Country(ies) involved México.

Other relevant information This systematic review is being registered retrospectively. The literature search, study selection, data extraction, risk-of-bias assessment, evidence synthesis, and manuscript preparation had already been conducted before submission of this INPLASY record. The registration is intended to transparently document the methods used in the review and does not represent prospective protocol registration.

Keywords obstructive sleep apnea; mandibular advancement device; CAD/CAM; 3D printing; digital dentistry; treatment adherence.

Dissemination plans The findings of this systematic review will be submitted for publication in a peer-reviewed scientific journal in the field of sleep medicine and dental sleep medicine. The results may also be disseminated through scientific and academic presentations.

Contributions of each author

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