

Technological Innovations in Oral Appliance Therapy for Obstructive Sleep Apnea: A Systematic Review of Advancements, Efficacy, and Patient-Centered Outcomes

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ABSTRACT

This systematic review evaluates recent technological advancements in oral appliance therapy for obstructive sleep apnea, with a focus on design innovations, efficacy, and patient-centered outcomes. Emerging materials, digital manufacturing techniques, and smart sensor integration have substantially improved the comfort, customization, and objective monitoring of mandibular advancement devices, leading to greater patient adherence and satisfaction compared to traditional CPAP therapy. The review synthesizes evidence from January 2018 to June 2025, highlighting that advanced oral appliances achieve clinically meaningful reductions in the Apnea-Hypopnea Index, enhance sleep quality, and offer favorable economic and scalability profiles for healthcare systems. These findings support the expanded use of technologically sophisticated oral appliances as a viable therapeutic option for OSA, especially among individuals intolerant to standard therapies, and underscore the need for further research into long-term safety and personalized device optimization.

INTRODUCTION

Obstructive sleep apnea (OSA), a pervasive sleep-related breathing disorder, involves recurrent upper airway collapse during sleep, leading to intermittent hypoxia and sleep fragmentation¹. This condition is associated with significant health risks, including cardiovascular disease, hypertension, and diminished quality of life^{2,3,4}. Continuous Positive Airway Pressure (CPAP) therapy remains the gold standard treatment for OSA due to its high efficacy in reducing polysomnographic indices^{5,6}. However, patient adherence to CPAP can be suboptimal, often limited by discomfort, claustrophobia, or perceived inconvenience⁶. This adherence challenge underscores the need for alternative, well-tolerated therapies⁷. Oral appliances (OAs), particularly mandibular advancement devices (MADs), offer a patient-friendly alternative, demonstrating comparable clinical effectiveness to CPAP in some patient subsets, especially those with mild to moderate OSA⁸.

Research Question and Objectives: This systematic review evaluates the impact of recent technological innovations on the design, functionality, and clinical outcomes of oral appliances for obstructive sleep apnea. The central inquiry is how advancements in materials, manufacturing processes, and integrated smart technologies contribute to enhanced efficacy, patient experience, and broader clinical applicability of OAs. Specific objectives include categorizing significant technological developments in OA therapy, assessing their influence on objective sleep parameters and subjective patient-reported outcomes, and identifying implications for future clinical practice and research directions.

Significance of Advancing Oral Appliance Therapy: Advancing oral appliance therapy holds substantial significance for

addressing the persistent adherence issues associated with CPAP, potentially increasing treatment uptake and long-term compliance for OSA patients⁹. By improving comfort, customization, and objective monitoring capabilities, technological innovations foster a more patient-centric approach to OSA management. This evolution positions OAs as an increasingly viable and accessible therapeutic solution, particularly for individuals unable or unwilling to use CPAP, thereby expanding treatment options and improving public health outcomes⁹.

Methodology

Systematic Review Design and Protocol Registration: This systematic review was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines¹⁰. The review protocol was prospectively registered in PROSPERO (Reg ID: CRD420251153927) ensuring transparency and reproducibility. The methodology aimed to provide a comprehensive and unbiased synthesis of the current evidence on technological innovations in oral appliances for OSA, focusing on their design, efficacy, and patient-centered outcomes. The quality of evidence and strength of recommendations were assessed using the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) system where applicable¹⁰.

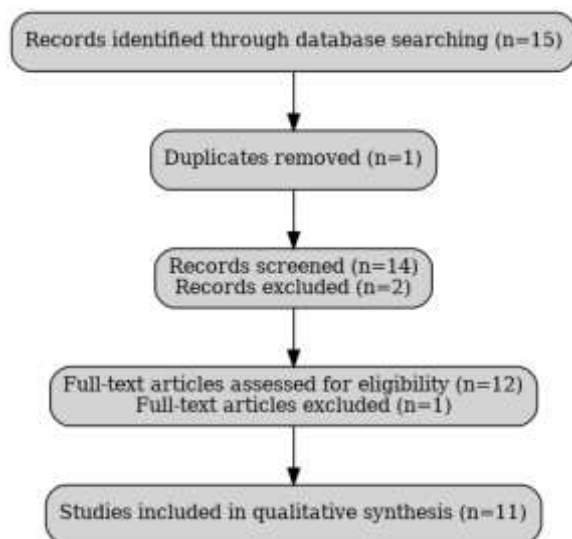
Eligibility Criteria and Study Selection: Studies were included if they investigated technological innovations in oral appliances, specifically mandibular advancement devices, for the treatment of adult patients with OSA. Eligibility criteria encompassed original research articles, randomized controlled trials (RCTs), systematic reviews, and meta-analyses published in peer-

reviewed journals. Studies focusing exclusively on pediatric populations, surgical interventions, or non-OSA related conditions were excluded. Publications without explicit mention of technological advancements in OA design, materials, or integrated features were also omitted. Two independent reviewers screened titles and abstracts, followed by full-text evaluation of potentially relevant articles, resolving discrepancies through consensus with a third reviewer.

Comprehensive Search Strategy: A comprehensive search was executed across electronic databases including PubMed, Embase,

and Cochrane Library. The search strategy combined Medical Subject Headings (MeSH) terms and keywords: ("obstructive sleep apnea" OR OSA) AND ("oral appliance" OR "mandibular advancement device") AND ("3D printing" OR "sensor" OR "biomaterial" OR "neuromuscular stimulation" OR "precision therapy") FILTER: 2018-2024

Date restrictions were applied from January 2018 to June 2025. Reference lists of identified relevant articles and existing systematic reviews were manually screened to identify additional pertinent studies not captured by the initial database searches.



Data Extraction and Synthesis Framework: Data extraction was performed by two independent reviewers using a standardized form, capturing information on study characteristics (e.g., design, sample size, duration), patient demographics, specific technological innovations investigated, intervention details (OA type, material, features), and outcome measures. Primary outcomes included objective measures such as Apnea-Hypopnea Index (AHI) reduction, oxygen saturation levels, and sleep architecture parameters. Secondary outcomes encompassed patient-reported measures, including Epworth Sleepiness Scale (ESS) scores, quality of life, treatment adherence, user satisfaction, and adverse events. Data synthesis involved a narrative approach, grouping studies by thematic innovation. Where appropriate and data permitted, quantitative synthesis (meta-analysis) was considered for homogenous outcomes, but the diverse nature of technological innovations often necessitated a qualitative, thematic review to identify trends and gaps in the literature.

Thematic Review of Technological Advancements in Oral Appliance Therapy

Evolution of Oral Appliance Design and Materials

Custom-Fit Devices and Digital Manufacturing Technologies: The evolution of oral appliance design has significantly benefited from digital manufacturing technologies, enabling the creation of highly customized devices. Three-dimensional (3D) printing has emerged as a transformative method, allowing for the production of thinner, lighter, and more precisely fitted OAs⁸. This advanced manufacturing process, transitioning from traditional dental impressions to 3D-printed models, promises increased availability and affordability, alongside improved patient comfort and retention¹⁰. Custom-made devices generally provide superior comfort and efficacy compared to non-individualized options¹¹, with some studies highlighting that monobloc designs, often amenable to custom fabrication, show higher success rates than duobloc counterparts in terms of AHI reduction and patient preference¹².

Innovations in Biocompatible Materials: Research into novel biocompatible materials has also progressed, aiming to enhance the durability, flexibility, and patient acceptance of OAs. Traditional OAs typically use various polymer types and metallic components, influencing factors such as rigidity, thickness, and weight⁸. Newer materials seek to minimize allergic reactions,

reduce irritation to oral tissues, and improve the overall longevity of the appliance. The selection of materials also influences the distribution of forces on dentition, tongue space, and retention mechanisms, all of which contribute to patient comfort and adherence⁵.

Smart And Connected Oral Appliances: Integration of Sensors and Monitoring Systems:

Real-Time Therapeutic Feedback and Adherence Monitoring:

The integration of sensors into oral appliances represents a significant technological leap. These smart OAs can provide real-time therapeutic feedback and objectively monitor adherence, a critical advancement given that subjective reporting often overestimates actual device usage⁹. Embedded temperature sensors, for instance, allow for precise tracking of wear time, enabling clinicians to assess compliance accurately⁸. This objective data supports individualized treatment adjustments and enhances the overall effectiveness of therapy. Such monitoring systems are particularly important for patients with severe OSA, where accurate adherence data directly impacts health outcomes¹¹.

Remote Patient Management and Data Analytics: Beyond adherence, advanced OAs facilitate remote patient management and data analytics. Systems capable of remotely controlling mandibular advancement during sleep offer the potential to identify optimal therapeutic positions and predict treatment success without requiring in-laboratory titration⁹. The use of smartphone applications to acoustically score snoring also contributes to monitoring symptom alleviation in mild OSA cases. This capability for continuous data collection and analysis empowers clinicians to make data-driven decisions, optimize treatment settings from a distance, and personalize care more effectively, thereby reducing the burden of frequent in-person visits.³

Biomechanical Optimization and Adaptive Designs

Adjustable Mechanisms For Individualized Therapy: Oral appliances feature adjustable mechanisms to facilitate individualized therapy. The optimal advancement position for a patient is not known a priori, necessitating careful clinical follow-up and symptom assessment⁸. Titratable OAs allow for incremental adjustments, often performed at home, to resolve OSA signs and symptoms. Adjustable OAs demonstrate a higher success rate than fixed designs⁷. The extent of mandibular

protrusion significantly impacts efficacy, with greater advancement often correlating with increased AHI reduction, though beyond a 50% advancement, the success rate may not substantially improve ¹¹.

Patient Comfort, Retention, and Minimization of Side Effects: Technological refinements also prioritize patient comfort and retention while minimizing side effects. Initial side effects such as dental and gingival tenderness, hypersalivation, dry mouth, or temporomandibular joint (TMJ) discomfort are common but typically resolve within two months ¹³. Persistent issues, particularly discomfort or the perceived "cumbersome" nature of treatment, can lead to discontinuation. Designs allowing for lateral mobility and adequate tongue space contribute to comfort. Mandibular exercises prior to OA use can mitigate TMJ pain and temporary bite changes, concurrently enhancing OAT adherence and improving quality of life ¹⁰. Long-term occlusal changes are common but infrequently prompt treatment discontinuation ⁸.

Impact Analysis: Efficacy, Patient Experience, And Clinical Implications

A. Comparative Effectiveness of Innovative Oral Appliances Versus Conventional Therapies:

Outcomes in Apnea-Hypopnea Index Reduction and Sleep Quality Improvement: Technologically advanced oral appliances demonstrate significant capabilities in reducing the Apnea-Hypopnea Index (AHI) and improving sleep quality. A key mechanism involves mandibular advancement, which dilates and stabilizes the pharyngeal airway, increasing the cross-sectional area, particularly in the retropalatal or velopharyngeal region ¹³. While CPAP typically achieves greater AHI reduction, OAs offer comparable clinical effectiveness due to higher patient adherence ⁹. In patients with moderate or severe OSA, OAs have reduced AHI by an average of 63.9% ¹⁴. Although AHI reduction is less pronounced than with CPAP, both therapies similarly improve subjective sleepiness, driving simulator performance, and disease-specific quality of life ⁷.

Long-Term Compliance and Treatment Adherence: Long-term adherence represents a major advantage of oral appliance therapy. Patients exhibit a greater likelihood of adhering to OA treatment compared to CPAP, often compensating for CPAP's higher efficacy in reducing polysomnographic indices ¹⁴. The long-term adherence rate for OAs is approximately 50% ⁸. Objective monitoring via embedded sensors significantly enhances the accuracy of adherence data, moving beyond subjective patient reports which can overestimate actual usage ¹⁵. This improved adherence contributes to sustained clinical benefits and better overall health outcomes ⁹.

B. Patient-Centered Outcomes and Quality of Life Enhancement

User Satisfaction, Usability, and Acceptability

Technological innovations in OAs contribute directly to heightened user satisfaction, usability, and acceptability. The ability to create custom-fit, comfortable, and adjustable devices significantly improves the patient experience ¹⁵. For instance, 83% of OA users report symptom relief, and patient satisfaction and willingness to recommend the treatment are high, often exceeding 85% ¹⁵. The ease of adjustment, allowance for lateral mobility, and optimized tongue space are key design features that enhance usability ⁸.

Mitigation of Adverse Events and Side Effects

While OAs are generally well-tolerated, side effects can occur, including dental and gingival tenderness, hypersalivation, and temporary occlusal changes ⁷. Technological advancements aim to mitigate these adverse events. For instance, mandibular exercises prior to sleep can reduce temporary bite changes and temporomandibular disorder (TMD) pain ². Although occlusal changes are common, they typically do not lead to treatment discontinuation ¹. Long-term use can lead to reduced overjet and overbite, and careful monitoring of dental changes is advised ¹⁶.

C. Healthcare System Implications: Cost-Efficiency and Accessibility

Economic Evaluation of Technologically Advanced Therapies: The economic evaluation of technologically advanced OAs suggests a favourable cost-efficiency profile, particularly when considering the high adherence rates. While CPAP remains highly effective, its cost-effectiveness can be borderline in milder cases, and its high intolerance rate often results in suboptimal real-world

effectiveness ¹⁷. OAs, with their lower initial cost and better patient acceptance, present a more economically viable long-term solution for a significant portion of the OSA population ¹¹. Decreasing 3D printing costs also contribute to increasing the affordability and availability of OAs (8).

Scalability and Integration into Clinical Practice: The scalability of advanced OA manufacturing, particularly through 3D printing, streamlines integration into broader clinical practice ⁵. The American Academy of Sleep Medicine (AASM) and American Academy of Dental Sleep Medicine (AADSM) recommend custom, titratable OAs for adult patients intolerant to CPAP or preferring alternative therapy ¹⁸. The integration of objective monitoring and remote management capabilities reduces the need for extensive in-person follow-ups, enhancing efficiency for both patients and healthcare providers ⁹. This facilitates wider adoption and makes effective OSA management accessible to a larger demographic.

CONCLUSION

Synthesis of Key Findings and Clinical Recommendations: This systematic review demonstrates the transformative role of technological innovations in enhancing oral appliance therapy for obstructive sleep apnea. Digital manufacturing, particularly 3D printing, facilitates the production of highly customized, comfortable, and lightweight devices, leading to improved patient acceptance and adherence ¹¹. The integration of smart sensors into OAs allows for objective adherence monitoring and real-time therapeutic feedback, moving beyond subjective reporting and enabling more precise treatment adjustments ⁸. While CPAP often achieves greater AHI reduction, the superior adherence associated with OAs contributes to comparable overall clinical effectiveness for many patients, especially those with mild to moderate OSA ⁵. Clinically, OAs are a viable and increasingly refined alternative, particularly for CPAP-intolerant patients, due to their enhanced patient-centered outcomes, including high satisfaction and mitigated side effects ¹⁵. The economic benefits of improved adherence and streamlined remote management further support their integration into standard clinical practice.

Future Directions for Research and Development in Oral Appliance Therapy: Continued research and development in oral appliance therapy should focus on several areas. Further exploration of biomechanical optimization, including adaptive designs that dynamically adjust based on sleep position or real-time airway dynamics, could refine efficacy ¹⁹. The development of more sophisticated embedded sensors for continuous physiological monitoring, beyond just adherence, offers potential for personalized therapy adjustments. Additionally, long-term studies are needed to comprehensively assess the impact of these technological advancements on dental and craniofacial structures, ensuring sustained patient safety and comfort ¹⁶. Predictive modeling, integrating patient-specific anatomical data with AI, could improve patient selection for OA therapy, moving beyond empirical titration ^{20,21}. Finally, comparative effectiveness research, including cost-benefit analyses of the newest generation of smart OAs versus traditional approaches, will be essential for guiding healthcare policy and resource allocation, solidifying the role of OAs as a technologically advanced solution for OSA management.

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