

Digital workflow to fabricate a 3D-printed monobloc mandibular advancement appliance for primary snoring and obstructive sleep apnoea

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Objective: Mandibular advancement appliances (MAAs) are used to treat primary snoring and obstructive sleep apnoea (OSA) by advancing the mandible to maintain upper airway patency during sleep. The conventional fabrication of custom-made MAAs requires skilled technicians and specialised laboratories, resulting in longer processing times and higher outsourcing costs. Advancements in 3D-printing technology offer an efficient in-office alternative. The present paper aims to demonstrate the potential of digital technology in fabricating in-office, 3D-printed, non-adjustable monobloc MAAs.

Methods: The fabrication and refinement processes of non-adjustable monobloc MAAs were carried out on three patients of whom two presented with primary snoring and one with mild OSA. The appliances were designed using Appliance Designer™ software (3Shape, Copenhagen, Denmark) and 3D-printed with a stereolithography printer (Uniz 3D printer, San Diego, US) using Ortho Flex resin (NextDent, The Netherlands).

Results: One MAA was made for each patient and incorporated specific refinement strategies to optimise fit and retention.

Improvements in snoring were noted in all patients. The Apnoea-Hypopnoea index (AHI) was normalised from 11.2 to 4.6 for the patient with mild OSA.

Conclusion: 3D-printed MAAs were successfully employed to manage patients presenting with primary snoring and mild OSA.

The digital workflow for fabricating 3D-printed MAAs, including refinement strategies to enhance fit and retention was presented, thereby laying the groundwork for future investigations and the development of in-office 3D-printed MAAs.

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Introduction

A Mandibular Advancement Appliance (MAA), also known as a Mandibular Advancement Device (MAD) or an Oral Appliance Therapy (OAT) device, is not only a primary solution to manage snoring issues^{1,2} but also recommended for individuals experiencing mild to moderate obstructive sleep apnoea (OSA) as well as patients with severe OSA

who may be unwilling or unable to tolerate Positive Airway Pressure (PAP) therapy.^{3,4}

Snoring is a sign of disordered breathing during sleep in which the upper airway vibrates audibly while breathing.¹ OSA is a sleep disorder marked by repetitive partial (hypopnoea) and/or complete cessation of ventilation⁵ (apnoea) secondary to partial or complete upper airway obstruction. The severity of OSA is

determined by the Apnoea-Hypopnoea Index (AHI), which ranges from mild ($5 < \text{AHI} < 15$), moderate ($15 < \text{AHI} < 30$), to severe ($\text{AHI} > 30$). Primary snoring, characterised by habitual snoring without associated apnoeas or hypopnoeas, is considered a benign condition and is not indicative of OSA.¹

Primary snorers and OSA patients as well as their bed partners, commonly experience loud snoring, daytime sleepiness, a lack of concentration, decreased work productivity, and a reduced quality of life due to sleep disruptions.^{6–10} Untreated OSA is often associated with co-morbidities related to hypertension, cardiovascular diseases, type 2 diabetes mellitus, cognitive deficits, and motor vehicle or workplace accidents, which have significant economic repercussions.^{11–13} The MAA works by shifting the tongue muscle base anteriorly and pushing the pharyngeal fat pads laterally and away from the airway, thereby reducing pharyngeal collapsibility during sleep.¹² Not only does the MAA significantly reduce the frequency and intensity of snoring, but has also been proven to manage OSA efficiently. It reduces AHI, the respiratory disturbance index (RDI), or the respiratory event index (REI), and improves minimum oxygen saturation, daytime sleepiness, systemic blood pressure, and health-related quality of life.¹⁴

Fabricating a custom-made MAA is a complex process, that requires specialised laboratories and experienced technicians. It is often outsourced, which incurs a higher treatment cost. The emergence of 3D printing has revolutionised this process, making appliance manufacture more feasible and efficient. MAAs can now be produced on-site thereby eliminating the need for specialised laboratories or costly outsourcing, which reduces the treatment costs and processing time, including titration and the replacement of broken or missing devices. Moreover, in-office production has the potential to support personalisation, especially related to MAA design.

The present paper presents a detailed digital workflow for the fabrication and refinement of non-adjustable monobloc MAAs using in-office 3D-printing technology.

Materials and Methods

Patient selection

Three patients who were deemed suitable and recommended for MAA treatment by a sleep physician were referred to an orthodontist. None of

the patients were obese or had other medical issues. The first two patients were primary snorers without OSA, while the third patient had mild OSA with an AHI of 11.2. The sleep physician conducted either a polysomnography (PSG) assessment or a home sleep apnoea test (HSAT) based on the patient's condition. The third patient underwent a Level 1 PSG with a scoring rule of 1a. Table I shows the patients' demographics and baseline data.

Digital Impression and bite registration

The dental arches were scanned using a 3D intraoral scanner (Trios 2 Pod Version; 3Shape, Copenhagen, Denmark). A George Gauge™ bite gauge (Great Lakes Orthodontics, USA) with a 5mm interincisal distance was used to determine the initial therapeutic position which is a vital part of the MAA titration protocol. It is defined as the starting position of the mandible when an MAA is delivered at the start of therapy.¹⁵ The initial therapeutic study position for the MAA was set at 50% of the maximum mandibular protruded excursion which was defined as the distance measured from the posterior reference point (the most retruded position) to maximal protrusion (the most protruded position). The occlusion at 50% of maximum mandibular protrusion held by the George Gauge™ bite gauge was then scanned digitally using the same 3D intraoral scanner (Figure 1) and imported into the Appliance Designer™ software (3Shape, Copenhagen, Denmark) to design the MAA.

Appliance design and 3D-printing

After designing the extension of the appliance (Figure 2), bilateral bars were created from the canines to the second molars to join the maxillary and mandibular appliances (Figure 3). The design (Figure 4A) was then added to the model-building platform of the stereolithography additive manufacturing 3D printer (Uniz 3D printer, San Diego, USA) (Figure 4B) and printed using Ortho Flex (NextDent, The Netherlands), a clear biocompatible Class IIa material¹⁶ developed for 3D-printed dental splints and retainers. Stereolithography uses ultraviolet light to create rigid layers from a sensitive liquid resin through layer-by-layer hardening until the entire model has been formed.

Table 1. Patients' demographics and baseline data

Patient	Age	Gender	Ethnicity	BMI	NC	Diagnosis	AHI	Mean lowest Oxygen Saturation	Incisor relationship	Sagittal Skeletal Pattern	Vertical Skeletal Pattern
1	32	Male	Chinese	Normal	Normal	Primary snorer	NA	NA	Class I	Class I	Normodivergent
2	33	Male	Chinese	Normal	Normal	Primary snorer	NA	NA	Class I	Class I	Normodivergent
3	38	Female	Chinese	Normal	Normal	Mild OSA	11.2	89%	Class I	Class II	Normodivergent

AHI, Apnoea-Hypopnoea Index; BMI, Body Mass Index; NA, Not applicable; NC, Neck circumference.



Figure 1. Virtual model with bite scanned at 50% of the maximum mandibular protrusive excursion and 5 mm interincisal vertical opening.

Post-processing protocol

After one and a half hours of printing, the appliance, along with the supports, were removed from the printer for cleaning. The MAA appliances were first soaked in 99.9% isopropyl alcohol (IPA) for 30 minutes to disinfect the surface and remove any uncured resin. After soaking, the support structures were carefully removed to avoid damaging the appliance. Finally, the appliance was exposed to UV

light for 30 minutes at 60°C for final polymerisation to fully cure any residual resin and so make the appliance safe for use. The MAA was then examined for sharp edges and trimmed using a tungsten carbide acrylic bur.

Fitting and delivery protocol

During the initial fitting, the MAA was separately adjusted to the upper and lower arches to ensure a proper fit. Once the fit was confirmed, the appliance was re-fitted to the upper arch. The patient was instructed to advance the lower jaw and gently close onto the lower part of the appliance. The patient was also instructed on how to insert and remove the appliance. Further instructions were provided regarding the wear regime and appliance care. The patients were advised to immediately contact the clinician if persistent discomfort was experienced or any unusual symptoms arose. So that the patients could acclimatise, each was evaluated within a month after receiving the MAA to identify any issues and reinforce compliance. Follow-up reviews for titration were scheduled at 6 to 8-week intervals. A new MAA

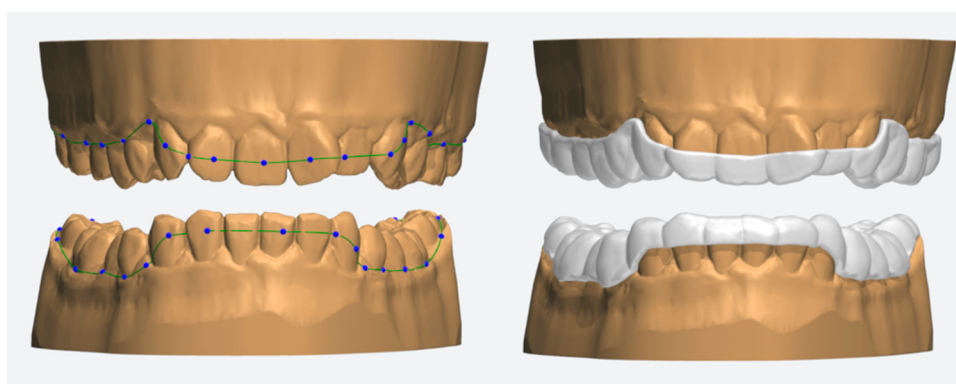


Figure 2. Marking of the extension of the plate on casts and its designated view.

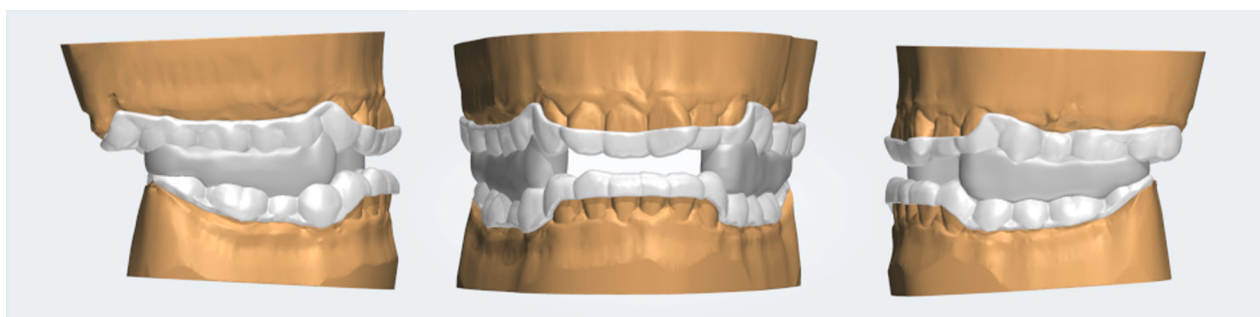


Figure 3. Addition of bilateral bars from canines to second molars.

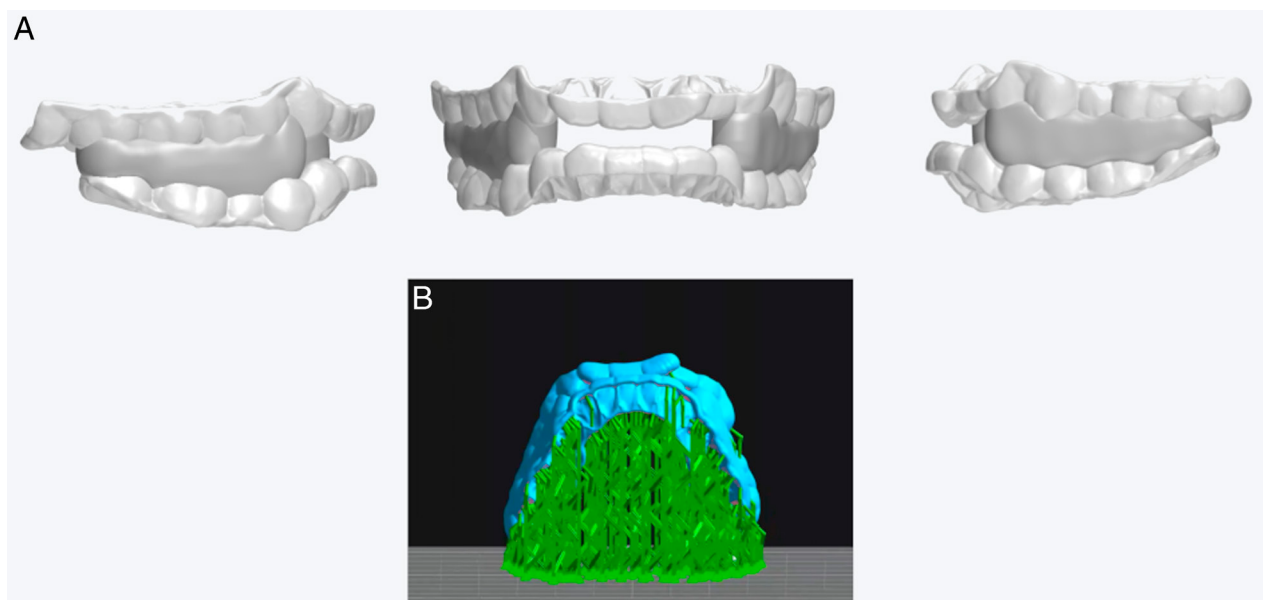


Figure 4. A, Final virtual MAA design; B, View of the virtual MAA with supports on the model-building platform.



Figure 5. A, 3D-printed MAA right lateral view; B, 3D-printed MAA frontal view; C, 3D-printed MAA left lateral view.



Figure 6. A, Patient's right lateral occlusal view; B, Patient's frontal occlusal view; C, Patient's left lateral occlusal view.

with a further increased or reduced mandibular advancement position would be prescribed based on the titration needs. Once acclimatised and titrated, patients with OSA were referred to the sleep physician for another Level 1a PSG, while wearing the MAA overnight in the sleep laboratory during the test. Appliance management was adjusted according to the PSG report if needed. All patients were scheduled for annual reviews with the orthodontist and the sleep physician.

Results

Table I summarises the demographic and baseline data of the patients.

Design 1 - initial design

The first patient presented with a persistent snoring problem which impacted his partner's sleep quality. He presented with a Class I incisor relationship on a Class I skeletal pattern with a complete dentition

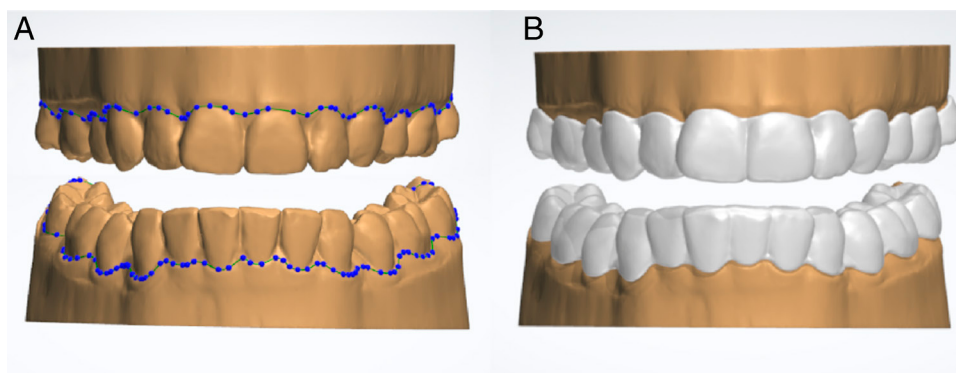


Figure 7. A, Marking of the extension; B, Virtual appliance following the marking.

and without periodontal problems. He was offered a MAA to manage primary snoring.

The MAA design extended up to the cervical margin of the buccal surfaces of the posterior teeth while covering only half of the anterior teeth (Figures 2–5). This design principle was recommended by Graf et al. who designed a twin block appliance with full coverage of the posterior teeth plus half coverage of the anterior teeth.¹⁷ The half coverage of the anterior teeth resembled a bow from canine to canine and avoided excessive undercuts, thereby ensuring ease and comfort in wearing and removing the appliance.

The fit was optimal, but retention was found to be only satisfactory. However, the patient tolerated the MAA well and expressed satisfaction. Snoring significantly reduced in both frequency and intensity, and the patient is currently undergoing an annual review.

Design 2 - retention refinement

The second patient presented with a similar snoring issue and also had a Class I incisor relationship on a Class I skeletal pattern. He had previously undergone orthodontic treatment and was not wearing retainers (Figure 6).

A refinement of the initial design was undertaken based on clinical observation of the less-than-ideal retention experienced by the first patient. A design incorporating full coverage of all the teeth including the anterior teeth was proposed (Figure 7). It was determined that the full coverage would not cause fitting issues as the teeth were relatively well-aligned, as a result of the previous orthodontic treatment.

The MAA was retentive but lacked a full fit in the anterior region (Figure 8D). By comparing the 3D-printed MAA with the virtual MAA design, it was speculated that there was a minor printing inaccuracy in the anterior region, where both the upper and lower segments collapsed towards each other by about 0.5mm to 1mm (Figure 8A and D). The patient tolerated the MAA well and expressed satisfaction with its use. There was a notable decrease in the frequency and intensity of snoring. The patient was satisfied with the treatment outcome and is currently undergoing annual reviews. Potential relapse of the upper and lower incisors due to the minor localised suboptimal fit was discussed, and the patient accepted the risk.

Design 3 – optimising anterior support

The third patient was also a post-orthodontic patient with a diagnosis of mild OSA as indicated by her Apnoea-Hypopnoea Index (AHI) of 11.2. She demonstrated a Class I incisor relationship on a Class II skeletal pattern.

As minor printing inaccuracy was encountered in the previous MAA, further refinement was considered. It was speculated that the collapse of the upper and lower anterior segments during printing was due to increased weight in the anterior region after incorporating full coverage of the incisors. The inadequacy of supports may lead to an inability to bear the weight of the anterior segment during the printing process. To address this issue, the bars were bilaterally extended up to the distal surface of the central incisors (Figure 9).



Figure 8. A, Bars addition; B, Virtual MAA design; C, 3D-printed MAA; D, Intraoral photographs of the MAA.

The final product achieved an acceptable fit (Figure 10) and resolved the issues related to the second design. A therapeutic position of 50% maximum mandibular protrusive excursion was confirmed during the titration phase through both subjective assessment and objective (PSG) evaluations. AHI showed a remarkable improvement from 11.2 to 4.6, with an Epworth Sleepiness Scale score of 5 and a snore intensity of 1. Other PSG outcomes before and after the treatment are shown in Table II.

The three patients were successfully managed at 50% of the maximum mandibular excursion, and none required another MAA for titration purposes. To date, the three patients have been reviewed for less than 12 months and are currently scheduled

for annual reviews with both the orthodontist and the sleep physician. None of the MAAs have been reported with any mechanical issues, identified as cracks, or patient medical issues, specifically related to allergies.

Discussion

The American Academy of Sleep Medicine (AASM) and the American Academy of Dental Sleep Medicine (AADSM) recommended custom-made MAAs and accompanying titration.¹⁴ Generally, there are two types of custom-made MAAs available commercially: an adjustable (monobloc or bibloc), or a non-adjustable (monobloc or bibloc), both of which deliver similar reductions in AHI and Oxygen

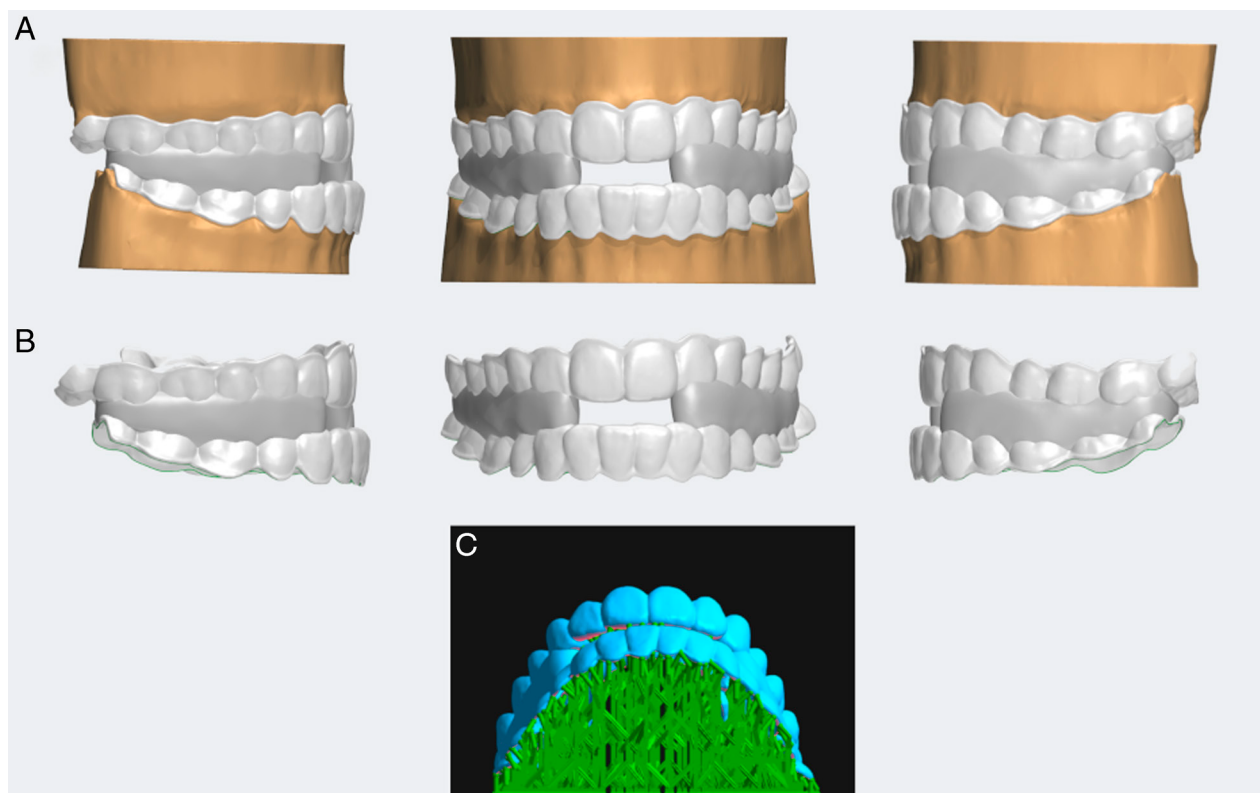


Figure 9. A, Extension of the bars to the lateral incisors; B, Virtual MAA design; C, View of the virtual MAA with supports on model-building platform.



Figure 10. A, The 3D-printed MAA; B, Patient wearing the 3D-printed MAA.

Desaturation Index (ODI).¹⁴ However, a non-adjustable MAA requires multiple MAA fabrication processes for titration compared to the adjustable MAA. In comparing the monobloc and bibloc, recent systematic reviews and meta-analyses have

provided low to moderate evidence and indicated that the monobloc (non-adjustable) MAA was more effective than the bibloc (adjustable or non-adjustable) MAA in reducing AHI, improving minimum oxygen saturation, achieving success, and

Table II. Sleep parameters for patient 3

	Date	AHI	Apnoea	Hypopnoeas	Sleep Architecture					Respiratory Event				Snore Index
					TST (min)	SE (%)	S1 (%)	S2 (%)	S3 (%)	REM (%)	Mean Lowest		Oxygen Desat.	
											Oxygen Sat.			
Before MAA	Feb 2023	11.20	5	57	332.5	87.5	23.2	53.4	1.2	9.3	89%	5	5	2+
With MAA	Nov 2023	4.62	0	26	338.0	89.5	10.0	44.0	26.0	20.0	94%	0	2 (all associated with hypopnoeas)	1

AHl, Apnoea-Hypopnoea Index; Desat., Desaturation; ESS, Epworth Sleepiness Scale; min, minute; REM, Rapid Eye Movement Sleep; Sat, Saturation; SE, Sleep Efficiency; S1, Stage 1; S2, Stage 2; S3, Stage 3; TST, Total Sleep Time; %, percentage.

satisfying a patient's preference. These differences in effectiveness are speculated to be due to the capacity of the monobloc to offer less vertical opening. While the bibloc allows for some vertical jaw opening, increased upper airway collapsibility occurs during sleep which impacts MAA efficiency.^{18–20}

The use of non-adjustable MAAs was explored in this report, due to their simplicity and cost-effectiveness. Additionally, the design took advantage of the monobloc MAA, which limited mouth opening during sleep and prevented clockwise rotation of the mandible, thereby enhancing appliance effectiveness. With the successful integration of 3D printing, it was aimed to gradually transition to adjustable MAA in future research. This stepwise approach provided a foundation and framework for future investigation and exploration of advanced features. Consequently, healthcare providers can leverage the principles outlined in this paper to develop customised solutions for their patients.

The advent of 3D printing technology has revolutionised the field of dentistry. Initially acclaimed for its application in producing implant guides and surgical stents,²¹ this cutting-edge technology is now being explored to manufacture other dental appliances, including crowns, dentures, retainers, and aligners,^{21,22} thereby catering to the diverse preferences and mechanical requirements of individual patients. An additional prime example of this orthodontic innovation was illustrated by Graf *et al.*, who successfully engineered 3D-printed twin block appliances. Using the CAD software, appliances can be meticulously tailored to suit the specific needs of patients, by adjusting designs, material thickness, extension, and appliance coverage to align with clinical requirements and individual oral conditions. Inspired by Graf's approach,¹⁷ the present study developed a fully digital workflow for fabricating MAA.

The established workflow for 3D-printed MAA can also translate into fabricating other oral appliances such as retainers and splints for temporomandibular joint disorders (TMD). Expanding 3D-printing technology applications promises to transform dental care by providing innovative solutions to address various clinical needs. The workflow for constructing a 3D-printed MAA may constitute valuable intellectual property, fostering further innovation in oral appliance therapy, and driving future research and industry development.

Due to the increasing popularity and greater accessibility of 3D printing technology, there has been a significant rise in the number of dental and orthodontic practices adopting 3D printing facilities. While the initial startup costs for fabricating 3D-printed MAAs may be high, this is a lesser concern for practices that already have established 3D printing capabilities as existing facilities can be leveraged to produce various dental appliances, including MAAs. When comparing in-office 3D printing to outsourcing, which can range from RM3000 to RM8000 in Malaysia, the in-office production of MAAs becomes a cost-effective solution. This shift may lead to reduced production costs, which creates more affordable treatment options. As a result, therapy may become more accessible for patients and healthcare systems, potentially lowering treatment fees and promoting equitable healthcare access for those in need of MAAs. Furthermore, in-office 3D printing enhances treatment options, particularly in settings in which traditional fabrication methods may be limited or prohibitively expensive due to the need for specialised technicians and the complexity of technique-sensitive procedures. Beyond cost savings, 3D printing significantly reduces processing times for adjustments, titrations, and the replacement of broken or lost MAAs. Additionally, 3D printing supports a higher level of personalisation in MAA design, thereby tailoring treatment to the specific needs of each patient. It is also environmentally friendly, as it reduces steps in the production process and eliminates the need for working models.

The literature and evidence regarding the performance of 3D-printed oral appliances is limited, with none specifically available for 3D-printed MAAs. However, the 3D-printed twin block appliance described by Graf *et al.*¹⁷ may serve as, or be modified into, a non-adjustable bibloc MAA. There are key differences between the design of the 3D-printed twin block appliances and the 3D-printed MAAs described in the present report. The former extends 2 mm beyond the gingival border, while the latter only covers the teeth, which aims for optimal comfort. Further research may explore these two designs in relation to retention and patient comfort. Being a bibloc, the 3D-printed twin block appliance does not restrict mouth opening during sleep, which may reduce the appliance's efficiency. A hook-like structure could be added to the design to allow the placement of intermaxillary elastics and therefore

minimise mouth opening during sleep. Additionally, an anterior opening can be incorporated if an anterior breathing space is desired, offering customisation and personalisation for the patient.

The initial therapeutic position of the three MAA designs was set at 50% of the maximum mandibular protrusive excursion. An effective initial therapeutic position optimises the time needed to reach the final therapeutic position for MAA titration. An initial therapeutic position of 50% maximum mandibular protrusion was selected because a published meta-analysis reported that treatment efficacy of mandibular protrusions at 50% and above shows no significant difference,²³ while a recent randomised controlled trial reported that MAA at 50% of maximum mandibular excursion improved AHI more effectively than MAA at 25%.²⁴ The only OSA patient who received the 3D-printed MAA presented in this report showed a remarkable improvement and normalisation of the AHI score from 11.2 to 4.6, with an Epworth Sleepiness Scale score of 5 and a snore intensity of 1, without side effects indicating no further titration was needed.

Continued exploration and innovation are key to advancing the use of 3D-printing technology in the field of sleep medicine, particularly in MAA design and fabrication. A larger clinical trial is warranted to further explore the efficacy of 3D-printed MAAs, including their impact on patient experience and quality of life. Furthermore, a comprehensive economic evaluation, including a cost-effectiveness analysis, which compares 3D printed MAAs with the conventional options will be of greater value for the body of evidence related to 3D printing technology for the management of OSA.

Conclusion

The comprehensive fabrication process and refinement strategies of the 3D-printed monobloc MAAs for three patients suffering from snoring and/or OSA were explored. The digital workflow for fabricating a 3D-printed MAA was presented, laying the groundwork for future investigations and the development of an adjustable MAA.

Conflict of interest

The authors declare that there is no conflict of interest.

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