Fake it till you custom-make it: a non-inferior thermoplastic mandibular advancement device?

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Oral appliances, of the mandibular advancement device (MAD) variety, are an effective treatment for obstructive sleep apnoea (OSA). In recent years, non-inferiority of MAD compared with continuous positive airway pressure (CPAP) in controlling important short-term health outcomes, like blood pressure, has been demonstrated, despite residual mild OSA on MAD treatment.[1 2] This equivalent effectiveness is potentially attributable to greater usage and treatment preference for MAD over CPAP which counteracts any inferior efficacy.[2]

It is well recognised that Apnoea Hypopnea Index (AHI) changes with MAD vary from individual to individual, with some patients achieving major improvement or resolution of OSA, and others left with varying degrees of residual OSA.[3] This uncertainty around therapeutic efficacy remains a clinical barrier. Therefore, MADs are generally reserved for second-line therapy in the event of CPAP failure, or preferentially for less severe and/or less obese patients who respond better on average, although these characteristics are of low accuracy in predicting MAD therapeutic response.[3] Despite years of interest in clinical prediction tools for MAD treatment outcomes, current methods either lack verifiable utility or feasibility for routine clinical use.[4]

The success of MAD therapy also depends on clinical expertise and follow-up and quality of the oral device itself. There are numerous device options which vary in sophistication and customisation. The current guideline for MAD therapy recommend a customised, titratable (allowing adjustment to level of mandibular protrusion) device, over a non-custom device.[5] However, this is a guideline only, due to limited device comparison trials. For customised MADs, titratable devices have been shown to have better efficacy than fixed, non-adjustable devices.[6] Several studies report clear benefits of customised devices over non-customised options.[7–9] However, the drawback of customisation is greater financial outlay and optimisation time, which ultimately may not produce the desired outcome in treatment response.

Non-customised or 'boil and bite' devices are prefabricated thermoplastic devices which soften on submersion in boiling water to allow the user to impress their teeth, with the impression setting as it cools. These devices are significantly cheaper, particularly as they can be applied outside of dental supervision. Previous studies of various thermoplastic devices with customised comparators have shown lower response rates.[7 9 10] Others have found no difference in AHI reduction compared with customised devices, but worse side effects or retention issues with the thermoplastic devices.[8 11] Meta-analysis of three cross-over trials found customised MADs produce better efficacy, quality of life improvement and are preferred over thermoplastic MADs.[12]

In this issue of *Thorax*, Pepin and colleagues present a parallel group, non-inferiority trial of two titratable devices: one thermoplastic and one customised acrylic.[13] The study recruited CPAP treatment failures or refusers who were non-obese (body mass index <30 kgm^2) with moderate–severe OSA (AHI >15). In per protocol analysis, a 1.9% difference in response rates between devices was reported, well within the preset non-inferiority margin of a 20% difference between groups. There were significantly more dropouts for those randomised to the thermoplastic device, and assuming dropouts were non-responders this difference increases to 11.2%, although still within the 20% non-inferiority margin. There was also no difference in a range of largely subjective health outcomes (sleepiness, snoring, health-related quality of life).

In terms of treatment response in this trial, a fairly liberal definition was adopted: either a 50% reduction in AHI from baseline or treatment AHI<10 events/hour. Without a dual requirement for a percentage reduction and meeting an AHI threshold, some marginal improvements could be classified as response. For example, a 50% AHI reduction could still leave a participant with moderate OSA, conversely with a pretreatment AHI of 15, only a 34% AHI reduction is required to drop below 10 and be classified as a responder. Despite this liberal response definition, the overall response rate for the customised MAD in this study was 51.7%. The study methods state a clinical consensus of a 20% non-inferiority margin for response rate between devices being meaningful, based on an expected response rate of 75%. In previous studies specifically in severe patients with OSA (AHI>30), a titratable MAD produced a post-treatment AHI <10 in 60.1%[6] and by a liberal response definition of >50% AHI reduction, a 70% response rate.[3] Therefore, it would seem the response rate of the comparator customised MAD, encompassing both these response definitions, might be a little low in comparison to the literature, particularly as participants were not obese, with only moderate OSA severity on average. Therefore, potential limitations in comparing performance to other customised devices must be considered.

This thermoplastic MAD appears to have been relatively well tolerated for the 2-month period. Although thermoplastic devices are significantly cheaper, if patients stop using them, then they are likely not cost-effective. In the current study, the side effect profiles differed, with more complaints of discomfort, excessive salivation and gag reflex with the thermoplastic MAD, although side effect improvement was reported at 2 months. In a previous study of thermoplastic MAD use after 6 months, the main complaint of non-users compared with users was 'ill-fitting', with 'uncomfortable' the most frequent reason for stopping 3 months post-purchase, although 82.9% of those continuing with the device reported usage >3 nights/week.[14] Side effects, compliance and efficacy of MADs may change over time. The present study was conducted over a 2-month period and next steps would be to know what happens over longer periods of use of the thermoplastic MAD. Self-reported usage was significantly better for the customised MAD group in this study; however, reported usage of the thermoplastic device was 5.76 nights/week for 5.2 hours/night.

The American Academy of Dental Sleep Medicine advises that qualified dentists

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provide MAD therapy and monitor patients for side effects or occlusal changes.[5] The most important concern with thermoplastic devices becoming popular is the elimination of a dental check to assess suitability for MAD therapy. Patients should have sufficient healthy teeth in both dental arches (including implants) to retain the device and be free of periodontal and temporomandibular disease.[15] A study of MAD contraindications in patients with OSA reported a rate of 34% of OSA, with around 16% of patients needing dental or periodontal care before using the MAD, and another 16% required close supervision and follow-up to avoid exacerbation of pre-existing problems.[16] If patients buy these appliances directly online, they may have contraindications they are not aware of, resulting in increased rate of side effects and lack of information about possible short-term and long-term risks potentially arising from device use. Under the current study protocol, a dentist administered and titrated the thermoplastic device, and it is important to appreciate that implementation without dental supervision may not produce equivalent outcomes. Bypassing dental review could be viewed as another cost saving but leaves patients with OSA at risk of adverse outcomes and complicating ongoing care.

One unknown from this trial, due to the parallel group design, is whether this thermoplastic device is able to accurately indicate the treatment outcome if graduating to a customised MAD. To date, cross-over trials which performed polysomnography on both customised and thermoplastic MAD in the same patients, have not found concordance in responses between the two devices.[9 12] This has suggested that thermoplastic devices are not suited as a prediction tool for customised MAD success. This would be a highly desirable use of a cheaper, thermoplastic device. It could be that this appliance has better success in mimicking the response to a customised device since it is titratable, but unfortunately this cannot be answered from the study design.

There is a wide range of MAD available from thermoplastic to customisable, but relatively few comparative studies of their performance, the current study is another step towards this. As material technology and design innovation in MAD devices continue to evolve, it is important to make these comparisons and revisit the concepts behind current clinical guidelines. The field of sleep medicine is evolving to recognise the heterogeneity of OSA and the need for personalised medicine approaches[17 18] and thermoplastic devices could have a role in the decision for customised MAD therapy. Cheaper and effective thermoplastic alternatives could make MAD therapy more accessible and address short-term therapeutic needs. However, possible long-term side effects due to poorer fit and material properties need to be thoroughly investigated. Since these devices are marketed directly to patients, there is the risk of patients with insufficient teeth and periodontal or temporomandibular disease using them, which would have detrimental effects on the teeth and the jaw joints. However, under dental supervision, this study shows short-term non-inferiority in efficacy rates to a customised comparator with good reported usage in that time frame.

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