Original Article

Oral Interventions for Obstructive Sleep Apnea

An Umbrella Review of the Effectiveness of Intraoral Appliances, Maxillary Expansion, and Maxillomandibular Advancement

Vasiliki Koretsi, Theodore Eliades, Spyridon N. Papageorgiou

Summary

Background: The effectiveness of intraoral appliances (IOA), maxillary expansion (ME), and maxillomandibular advancement (MMA) in the treatment of children and adults with obstructive sleep apnea (OSA) has not yet been adequately assessed.

Methods: An umbrella review was performed based on established guidelines for evidence-based medicine. Data synthesis was performed only from randomized controlled trials with Paule-Mandel random-effects meta-analyses / meta-regressions using mean differences (MDs) and 95% confidence intervals (CIs) and was followed by the qualitative evaluation of the meta-evidence.

Results: 29 systematic reviews were included, 7 of which provided quantitative data. IOA were effective in improving apnea hypopnea index (AHI) compared to both, placebo appliances (12 trials; 525 patients; MD = –11.70; 95% CI: [–15.38; –8.01]; p<0.001) and no treatment (1 trial; 24 patients; MD = –14.30; [–21.59; –7.01]; p<0.001). Only the former comparison was supported by robust meta-evidence. Effectiveness of IOA as measured by the Epworth Sleepiness Scale, on the other hand, was not supported by robust meta-evidence. No randomized or prospective controlled trials were found on the effectiveness of ME (conventional or surgically assisted) and MMA.

Conclusion: Intraoral appliances are effective in reducing AHI and their use is substantiated by robust evidence. There is no evidence from high-quality research to support treatment with ME (conventional or surgically assisted) or MMA in patients with OSA.

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Obstructive sleep apnea (OSA) is a sleep-related disorder in which the repetitive narrowing or collapse of the upper airway leads to a partial decrease in airflow (hypopnea) or to complete airflow cessation (apnea) during sleep (1).

OSA is a common medical condition that affects 1% to 4% of children, with a higher prevalence in boys than in girls (2), as well as 2% to 5% of women and 3% to 7% of men (3).

Risk factors for OSA development include:

- Posterior position of the mandible (4, 5)
- Obesity (6, 7)
- Menopause (8, 9)
- High nasal airway resistance (10, 11)
- Smoking (12, 13).

An overview of the pathophysiology of OSA and associated risk factors is given in *Figure 1* (adapted with permission from Jordan et al. [14]).

Since some well-established risk factors have a genetic background, OSA aggregates within families (15). However, susceptibility to OSA among family members is not fully explained by familial aggregation of other risk factors, such as obesity (16, 17).

The impact of OSA on patients is considerable. Lack of energy seems to be the most important complaint (18), although daytime sleepiness is also reported by 46–47% of OSA patients (18, 19).

Additionally, OSA sufferers have an elevated risk of motor vehicle crashes, although the actual number of accidents is still quite low (20). Furthermore, their cognitive performance is impaired in proportion to OSA severity (21, 22), while their perceived quality of life appears to resemble that of other chronic diseases (23).

Available symptomatic or causative treatments include (24, 25):

- Lifestyle interventions—especially weight loss
- Intraoral appliances (IOA)
- Continuous positive airway pressure (CPAP)
- Pharmacological agents
- Surgery.

Additionally, in orthodontics, maxillary expansion has been thought to increase the upper airway dimensions and thus alleviate OSA symptoms (26). Overall, dental science is implicated in many OSA treatment

The clinical perspective

Intraoral appliances (IOA) for the treatment of obstructive sleep apnea (OSA) work mechanically, by holding and stabilizing the mandible in a forward position and thus increasing the upper airway dimensions. Custom IOA based on dental impressions are believed to be more effective than pre-fabricated ones and cooperation with a qualified dentist / orthodontist is desired. IOA are usually used in patients with mild to moderate OSA and those with severe OSA who cannot tolerate continuous positive airway pressure.

Rapid maxillary expansion to treat maxillary constriction can be performed in growing children by orthodontists. It opens the midpalatal suture and leads to a transverse expansion of the maxilla. Apart from the benefits of a balanced occlusion, this increases the nasopharyngeal airway and reduces nasal resistance facilitating nasal breathing. It is also believed to lead to anterior repositioning of the tongue.

Surgically assisted rapid maxillary expansion to treat maxillary constriction is performed in adults by maxillofacial surgeons and orthodontists cooperatively. In adults, due to the ossification of the midpalatal suture, maxillary expansion needs to be surgically assisted in order to obtain maximal skeletal changes, as it will otherwise lead to dentoalveolar compensation (tipping of teeth). Adults enjoy the same treatment benefits as children.

Maxillomandibular advancement (MMA) is performed in adults by maxillofacial surgeons in cooperation with orthodontists. It advances the maxillomandibular complex in the sagittal plane, thereby increasing the dimensions of the upper airway and the tone of the pharyngeal muscles. MMA is not a routine treatment in OSA and has to be anatomically indicated and carefully planned. Cephalometric analyses provide crucial help in identifying the anatomical site(s) of obstruction and in defining the limits of advancement to preserve facial aesthetics postoperatively.

modalities including IOA, rapid maxillary expansion (RME) in children, surgically assisted rapid maxillary expansion (SARME) in adults, and surgical maxillomandibular advancement (MMA) (24–30).

Here, we aimed to comparatively investigate the effectiveness of OSA treatment modalities for children and adults that are of interest to dentists/orthodontists by conducting an umbrella review of systematic reviews. Furthermore, we intended to systematically assess the available scientific evidence on these interventions and to identify potential biases that could affect the study findings.

Methods

Protocol, registration, conduct, and reporting

The protocol for this study was made a priori and registered in PROSPERO (CRD42016045840). All post hoc changes are appropriately mentioned. The review was conducted according to the Cochrane Handbook (31) and reported according to the PRISMA statement (32). We also considered the guidelines provided by Aromataris et al. (33).

Eligibility criteria, study identification and selection

Three search queries were created and appropriately adjusted to each electronic database for a systematic search from database inception to August 14th, 2016 *(eTable 1)*. Firstly, systematic reviews were checked for eligibility according to the criteria for systematic reviews listed in *eBox 1*. Secondly, all primary studies of each included systematic review were extracted and assessed according to the eligibility criteria for primary studies *(eBox 1)*. A detailed methodological description is provided in the *eMethods*.

Data extraction

Two authors (VK and SNP) independently extracted descriptive data from each eligible systematic review. For further data extraction of quantitative results from primary studies, we considered only such systematic reviews in which meta-analyses with comparison groups were performed. If an article presented separate meta-analyses on more than one eligible outcome, those outcomes were assessed separately. Data extraction was based on the results provided in the included systematic reviews; where discrepancies existed between reviews, we directly extracted data from their corresponding primary studies. For the predefined subgroup analyses, additional data were directly extracted from the primary studies. For further details, refer to the *eMethods*.

Assessment of pooled effects and heterogeneity

For meta-analyses of continuous outcomes, mean differences (MDs) of the treatment-induced increments were chosen as effect estimates, while risk ratios (RRs) were chosen for categorical outcomes, both with their 95% confidence intervals (CI). Based on clinical and statistical reasoning (e3), we estimated all pooled effects with a random-effects model using the Paule–Mandel estimator instead of the commonly used DerSimonian–Laird, due to the improved performance of the former (e4). All calculations were performed in STATA SE version 12 (StataCorp, College Station, TX, USA). Further details on the assessment of pooled effects and heterogeneity, assessment of small-study effects, and criteria for epidemiological associations are provided in the *eMethods*.

FIGURE 1

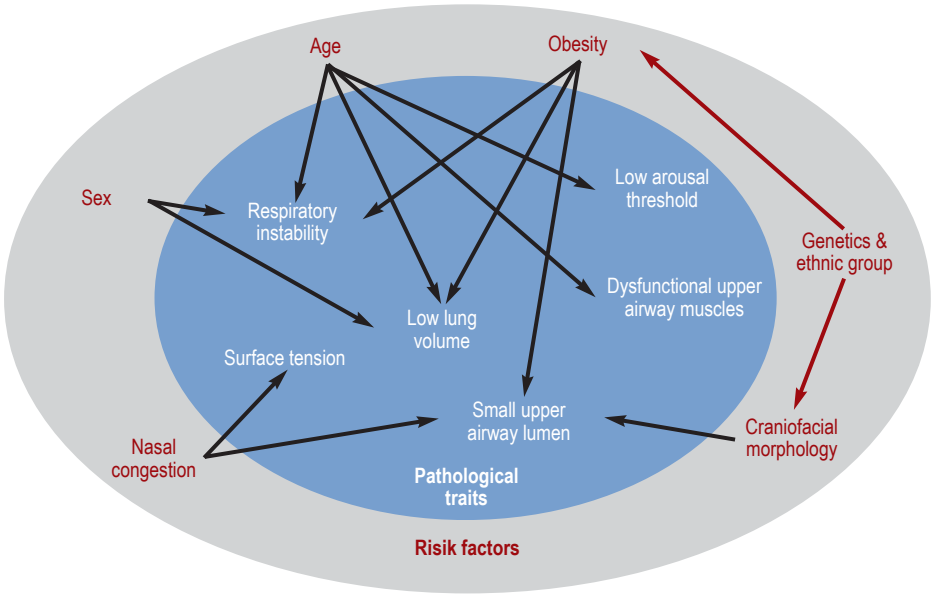


Diagram summarizing the pathophysiology of obstructive sleep apnea [adapted with permission from Jordan et al. (14)]

Results

Characteristics of included systematic reviews

The electronic searches yielded a total of 497 hits *(eFigure 1)*. After excluding inappropriate studies *(eTable 2)*, a total of 29 systematic reviews remained for inclusion in our study. *Table 1* provides an overview of the characteristics of the included systematic reviews and *eBox 2* gives a detailed description.

Risk of bias and methodological adequacy

Table 1 reports on the assessment of risk of bias in the included systematic reviews and *eTable 3* provides results for their methodological adequacy. A detailed description is provided in *eBox 3*.

Pooled effect sizes

Of the included systematic reviews, 18 (62%) performed meta-analyses of primary studies of any kind. After applying the eligibility criteria to their corresponding primary studies (including primary studies with comparison groups and excluding inappropriate study designs), data from 7 systematic reviews based on 20 primary studies *(eBox 4)* were extracted. After removing duplicate primary trials and pooling studies on the same comparison identified from different systematic reviews, 8 meta-analyses of cumulative evidence could be conducted for the primary outcome apnea hypopnea index (AHI) and the secondary outcomes Epworth Sleepiness Scale (ESS) and minimum oxygen saturation (MOS). These meta-analyses pertained to comparisons of IOA with placebo appliances, no treatment, or different appliances (custom IOA based on impressions, pre-fabricated IOA, or tongue suction IOA) in the treatment of OSA in adults *(Table 2)*. No comparisons were available for RME, SARME, or MMA.

As far as the comparison of IOA versus placebo appliances is concerned *(Table 2; Figure 2)*, a considerable improvement was evident with IOA in apnea hypopnea index scores (MD: –11.7; 95% CI: [–15.38; –8.01]; p<0.001), small, marginally non-significant effects were noticed on Epworth Sleepiness Scale scores (MD: –1.18 [–2.38; 0.03]; p = 0.055), and moderate effects on minimum oxygen saturation (MD: 3.33 [1.38; 5.28]; p = 0.007). High heterogeneity (I^2 >75%) was found in the meta-analyses of AHI and MOS. However, this posed a threat to the results only for the latter meta-analysis. For the former meta-analysis, the 95% prediction interval that incorporates existing heterogeneity was consistent to the left side of the forest plot. Additionally, compared to no treatment, IOA were found effective in improving AHI (MD: –14.30 [–21.59; –7.01]; p <0.001 as continuous and RR: 0.37 [0.15; 0.90]; p = 0.029 as binary outcome), but not in improving ESS (MD: –1.00 [–3.77; 1.77]; p = 0.479). Finally, as far as comparisons between different appliance designs are concerned, increased vertical opening (14 mm instead of 4 mm) did not influence AHI (MD: –2.00 [–6.51; 2.51]; p = 0.385) and significantly hampered improvement in ESS (MD: –6.00 [–8.41; –3.59]; p <0.001). However, this was based on a single trial and additional evidence is needed before any robust conclusions can be drawn.

Associations meeting the epidemiological criteria

From the cumulative evidence on the performance of IOA, only the large improvement in AHI compared to

TABLE 1

Characteristics of included systematic reviews

Nr.	Systematic review	Databases searched	Tx	Internal validity	Outcomes [*1]	MA	Evidence quality	Conflict of Interest
1	Abdullatif (2016) (e11)	9	ME	NICE tool	AHI, Min satur	Yes	No	NR
2	Ahrens (2011) (e12)	4	IOA	AASM criteria	AHI, RDI	No	No	External, non-profit
3	Bartolucci (2016) (e13)	6	IOA	EPHPP tool	AHI	Yes	GRADE	None existing
4	Bratton (2015) (e14)	2	IOA	Cochrane RoB	ESS	Yes	No	External / internal non-profit
5	Bridgman and Dunn (2000) (e15)	4	MMA	Jadad scale	OD	No	No	External, non-profit
6	Caldas (2009) (e16)	1	IOA	Jadad scale	AHI, ESS, OD	No	No	NR
7	Camacho (2015) (e17)	4	MMA	NICE tool	AHI, RDI, ESS, Min satur	Yes	No	External, non-profit
8	Caples (2010) (e18) [*2]	4	MMA	NR	AHI	Yes	GRADE	External for one author, research support from ResMed and Ventus Medical
9	Carvalho (2007, 2016) (e19, e20)	6	IOA	Cochrane RoB	AHI	No	GRADE	External, non-profit
10	Health Quality Ontario (2009) (e21)	6	IOA	Custom (Goodman)	AHI, ESS	Yes	GRADE	None existing
11	Hoekema (2004) (e22)	4	IOA	Custom (e41)	AHI, ESS	Yes	No	External, non-profit
12	Holty and Guilleminault (2010) (e23)	1	MMA	–	AHI, ESS, Min satur, SE	Yes	No	None existing
13	Hsieh and Liao (2013) (e24)	1	MMA	Jadad scale	AHI	No	No	External, non-profit
14	Huynh (2016) (e25)	4	IOA, ME	ARRIVE (modif. for humans)	AHI, OS	Yes	No	None existing
15	Knudsen (2015) (e26)	2	MMA	–	AHI, Min satur	Yes	No	None existing
16	Li (2013) (e27)	3	IOA	Cochrane RoB	AHI, ESS, Min satur	Yes	No	None existing
17	Lim (2004) (e28)	2	IOA	Jadad scale	AHI, Min satur	Yes	No	External, non-profit
18	Machado-Júnior (2016) (e29)	1	ME	–	AHI	Yes	No	None existing
19	Marcus (2012) (e30)	6	ME	AAN criteria	AHI	No	AAP criteria	None existing
20	Marklund (2012) (e31)	2	IOA	CEBM criteria	AHI, ESS, OS	No	CEBM criteria	None existing
21	Nazarali (2015) (e32)	6	IOA	Cochrane RoB	AHI, OD	No	No	NR
22	Okuno (2014) (e33)	3	IOA	Cochrane RoB (modif.)	AHI, ESS	Yes	GRADE	None existing
23	Pirklbauer (2011) (e34)	1	MMA	CEBM criteria	AHI, ESS	No	No	NR
24	Ramar (2015) (e35)	2	IOA	Cochrane RoB (modif.)	AHI, RDI, ESS, Min satur, SE	Yes	GRADE	External for some authors, profit / non-profit
25	Serra-Torres (2016) (e36)	3	IOA	CONSORT	AHI, ESS, OS	No	No	None existing
26	Sharples (2016) (e37)	3 & existing database	IOA	Jadad scale	AHI, ESS	Yes	No	None existing
27	Sher (1996) (e38)	1	MMA	-	AHI, Min satur	No	No	NR
28	Zaghi (2016) (e39)	4	MMA	NR	AHI, RDI	Yes	No	None existing
29	Zhu (2015) (e40)	5	IOA	Cochrane RoB	AHI, ESS, Min satur, SE	Yes	GRADE	External, non-profit

AAN, American Academy of Neurology; AAP, American Academy of Pediatrics; AASM, American Academy Sleep Medicine; AHI, apnea hypopnea index; CEBM, Center for Evidence-Based Medicine in Oxford; EPHPP, Effective Public Health Practice Project; ESS, Epworth Sleepiness Scale; Min Satur, mimimum oxygen saturation; MA, meta-analysis; ME, maxillary expansion; MMA, maxillomandibular advancement; NR, not reported; IOA, intraoral appliances; OD, oxygen desaturation; OS, oxygen saturation; RDI, respiratory disturbance index; SE, sleep efficiency; Tx, treatment.

[*1] Only among those that were included in our study protocol

[*2] Data extracted only on MMA

TABLE 2

Results of available comparisons regarding the primary and secondary outcomes in adult patients with obstructive sleep apnea

	Outcome	Trials	Patients	Effect (95% CI)	p value	Sign.	Heterogeneity				Largest trial	Egger's test
							τ^2	I^2	Comment	Consistent	Effect (95% CI)	Sign.
Intraoral appliance versus placebo appliance												
A	AHI_{con} *1	12	525	MD: −11.7 [−15.38; −8.01]	<0.001	**	20.2	93.6 %	High	Yes	−9.3 [−12.00; −6.60]	NS
B	ESS*2	11	475	MD: −1.18 [−2.38; 0.03]	0.055		2.1	60.6 %	Moderate	No	−2. 01 [−2.70; −1.32]	NS
C	Min satur*3	6	286	MD: 3.33 [1.38; 5. 28]	0.007	*	2.2	96.8 %	High	Yes	1.90 [0.51; 3.29]	–
Intraoral appliance versus no appliance												
D	AHI_{con}	1	24	MD: −14.30 [−21.59; −7.01]	<0.001	**	–	–	–	–	Same	–
E	AHI_{bin}	1	23	RR: 0.37 [0.15; 0.90]	0.029	*	–	–	–	–	Same	–
F	ESS	1	23	MD: −1.00 [−3.77; 1.77]	0.479		–	–	–	–	Same	–
Intraoral appliance$_1$ versus intraoral appliance$_2$												
G	AHI	1	23	MD: −2.00 [−6.51; 2.51]	0.385		–	–	–	–	Same	–
Intraoral appliance$_1$ versus intraoral appliance$_2$												
H	ESS	1	67	MD: – 6.00 [−8.41; −3.59]	<0.001	**	–	–	–	–	Same	–

AHI, apnea hypopnea index; con, continuous; bin, binary; CI, confidence interval; ESS, Epworth Sleepiness Scale; MD, mean difference; Min Satur, mimimum oxygen saturation; Sign., statistically significant at 5%.

intraoral appliance$_1$, intraoral appliance with 4 mm opening; intraoral appliance$_2$, intraoral appliance with 14 mm opening

*1 95% Predictive Intervals; Estimate: –22.55,–0.85; Consistent: Yes

*2 95% Predictive Intervals; Estimate: –4.76,2.40; Consistent: No

*3 95% Predictive Intervals; Estimate: –1.62,8.28; Consistent: No

placebo appliances was supported by robust evidence, i.e. sample sizes were adequate, heterogeneity was not an issue, the random-effects predictive intervals were consistent in favour of the intervention, and no signs of reporting bias were found *(Table 3)*.

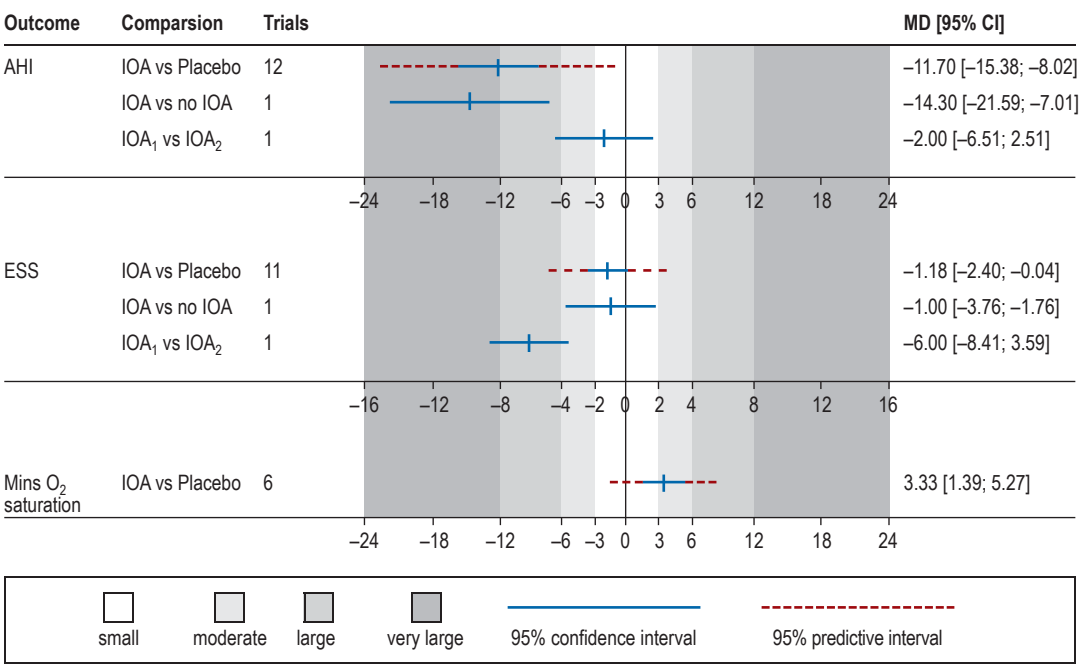
Discussion

This umbrella review of systematic reviews summarizes the existing evidence from randomized trials on the effectiveness of IOA, RME, SARME, and MMA in the treatment of OSA. A total of 29 systematic reviews were included in the qualitative synthesis, while eligible trials from 7 of these also contributed to the quantitative synthesis. Comparisons were available only for IOA, since for RME, SARME, and MMA no high-quality evidence was identified.

Considerable evidence indicated that IOA are effective in treating OSA in adults and improving AHI compared to both placebo appliances and no treatment. The former comparison was the only one that met all the criteria for strong epidemiological associations (e42) indicating strength of evidence. By mechanically holding the mandible in a forward position, IOA not only affect the anteroposterior dimension but also provoke an increase in the lateral diameter of the velopharynx (e43). In growing children with malocclusion, functional appliances for stimulating mandibular growth may alleviate OSA symptoms (e44, e45), but evidence is scarce and thus more research is needed. In regard to the secondary outcomes, IOA might have a positive effect on ESS and MOS in adults *(Table 2)*. However, the epidemiological strength of the associations (e42, e49) was poor, mostly due to the limited number of contributing studies.

As far as modifying factors on the effectiveness of IOA are concerned, subgroup analyses and meta-regressions indicated that baseline AHI levels were significantly associated with the observed AHI reduction *(eTable 4)*. This could mean that patients with more severe OSA symptoms are more likely to experience greater improvements in AHI. The same association between baseline severity and improvement of symptoms was also noticed for the effect of IOA on MOS *(eTable 5)*, but not ESS *(eTable 6)*. Although there were some indications pointing to small-study effects, these were not confirmed with the Egger's test. Furthermore, this association could also be explained by "regression to the mean" and needs further confirmation. It is also important to note, that OSA baseline severity might directly influence treatment choices (30) leading to IOA being used more often in mild to moderate cases with non-compliance to CPAP, since CPAP appears to be more effective in complete resolution of OSA compared to IOA (28). Although IOA are not as effective as the first-line option, CPAP, in reducing AHI, they might be better preferred by patients (e47, e48), since CPAP is associated with more serious negative aspects, which influence adherence (e48, e49) and thus the effectiveness of

FIGURE 2



Forest plot providing an overview of included meta-analyses and their results

MD, mean difference; CI, confidence interval; AHI, apnea hypopnea index; IOA, intraoral appliance; IOA_1 vs IOA_2, intraoral appliance (4 mm opening) versus intraoral appliance (14 mm opening); ESS, Epworth Sleepiness Scale

TABLE 3

Results on epidemiological criteria regarding the primary and secondary outcomes

	Outcome	p<0.001	Adequate sample size	Heterogeneity not a problem	PrI consistent	Egger's test NS	Criteria met
Intraoral appliance versus placebo appliance							
A	AHI_{con}	Yes	Yes	Yes	Yes	Yes	Yes
B	ESS	No	No	No	No	Yes	No
C	Min satur	No	No	Yes	No	–	No
Intraoral appliance versus no appliance							
D	AHI_{con}	Yes	No	–	–	–	No
E	AHI_{bin}	No	No	–	–	–	No
F	ESS	No	No	–	–	–	No
Intraoral $appliance_1$ versus intraoral $appliance_2$							
G	AHI	No	No	–	–	–	No
H	ESS	Yes	No	–	–	–	No

PrI, predictive intervals; NS, not significant; AHI, apnea hypopnea index; Min Satur, minimum oxygen saturation; ESS, Epworth Sleepiness Scale; con, continuous; bin, binary; intraoral $appliance_1$, intraoral appliance with 4 mm opening; intraoral $appliance_2$, intraoral appliance with 14 mm opening

Key messages

- According to the criteria for robust epidemiological associations, intraoral appliances (IOA) are effective in reducing apnea hypopnea index (AHI) in adult patients with obstructive sleep apnea (OSA) and this cannot be explained by placebo effects.
- The epidemiological evidence for the effect of IOA on Epworth Sleepiness Scale scores and minimum oxygen saturation in adult OSA patients was poor.
- There is no robust scientific evidence to support treatment of OSA patients with rapid maxillary expansion (RME), surgically assisted rapid maxillary expansion (SARME), or surgical maxillomandibular advancement (MMA).

treatment. Due to this fact, IOA could be used alternatively to CPAP in mild to moderate OSA and in severe OSA, if CPAP is not tolerated (30).

Although RME, SARME, and MMA in the treatment of OSA are not supported by robust evidence, the existing literature points to their possible effectiveness. In a randomized crossover trial comparing RME with adenotonsillectomy in children, AHI was reduced after RME in the first arm of the trial (e50). This reduction remained stable after 36 months (e51). In adults, SARME with mini-implants reduced AHI postoperatively (e52). Finally, although existing literature on MMA is mainly comprised by inappropriate study designs, MMA seems to be as effective as CPAP, with AHI pre- and postoperatively comparable to AHI pre- and post-CPAP (e53).

Strengths and limitations

- The present umbrella review was based on robust methodology (e42, e49) that was set out a priori and registered in PROSPERO (e54).
- Study selection and data extraction were performed on the level of the primary studies included in the identified systematic reviews. As a result, not only was the accuracy of extracted data ensured, but also only data from randomized trials were pooled (since no prospective non-randomized studies were found).
- The Paule–Mandel estimator of random-effects model was used as it outperforms the DerSimonian–Laird variance estimator (e4).
- The robustness of existing cumulative meta-evidence was judged on the basis of valid protocols of epidemiological strength (e42, e49).

On the other hand, several limitations should be considered in the interpretation of our findings:

- We might have missed some individual studies, if these had not been identified and included in the original systematic reviews.
- Most of the included systematic reviews had serious methodological inadequacies.
- Funnel plot asymmetry was consistently investigated with Egger's test for all meta-analyses, following the practice used in previous umbrella reviews (e42, e49, e55), although less than 10 trials were included in every case (e9).

Conflict of interest statement
The authors declare that no conflict of interest exists.

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► **Supplementary material**
For eReferences please refer to:
www.aerzteblatt-international.de/ref1218

eMethods, eBoxes, eFigure, eTables:
www.aerzteblatt-international.de/18m0200

Supplementary material to:

Oral Interventions for Obstructive Sleep Apnea

An Umbrella Review of the Effectiveness of Intraoral Appliances, Maxillary Expansion, and Maxillomandibular Advancement

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eMETHODS

Eligibility criteria, study identification and selection

No limitations on publication date, language, and status were applied to our searches. Additional hand searches of the reference lists of eligible articles were undertaken. Finally, two electronic databases (Google Scholar and PROSPERO) were manually searched for additional systematic reviews and / or protocols.

Eligibility of systematic reviews was assessed on the basis of title, abstract, and full text. Authors were contacted whenever a full text could not be found. Study identification and selection were performed by one reviewer (VK) with a subsequent independent duplicate check by a second reviewer (SNP). Disagreements were resolved by discussion with a third party (TE).

For adults, OSA was defined as having an apnea-hypopnea index (AHI) of at least five episodes per hour of sleep or a respiratory disturbance index of at least five episodes per hour of sleep (34). For children, OSA was defined as having an AHI of at least one episode per hour of sleep (35, 36). Primary trials included in systematic reviews had to be randomized clinical trials or prospective non-randomized controlled trials from any type of clinical setting. We excluded studies with retrospective or historical-experimental control groups as they are associated with bias (37, 38).

Data extraction

For each included systematic review, we recorded whether or not their primary studies had been assessed for risk of bias and whether the quality of evidence had been assessed according to the GRADE approach (39). However, we did not perform these procedures ourselves, as this task was beyond the scope of this umbrella review of systematic reviews. The methodological quality of the included systematic reviews was further appraised using the AMSTAR tool (40).

From each eligible meta-analysis, the same two authors (VK and SNP) independently extracted information on first author, year of publication, outcome(s) examined, number of included primary studies, and reported data at the individual trial level. Eligible outcomes were extracted in either continuous or binary format. In order to deal with study overlaps across the included meta-analyses, the PubMed Unique Identifier (PMID) was used to characterize each trial included in the meta-analyses. All available trials were pooled according to PMID.

After checking for design suitability and lack or proper handling by the trialists of carry-over effects (31, e1), we decided to include and combine both parallel and crossover randomized trials, approximating a paired analysis for the latter. We extracted for each outcome the absolute increment of change through treatment as final minus baseline value. In case this was not reported in the original trials, we calculated this ourselves using appropriate methods for paired data (31), using a pre–post correlation of 0.5 from existing data (e2). For crossover trials, we additionally calculated the effect size by subtracting the increment of change from baseline of each trial arm using a similar paired approach (e1) and a correlation of 0.25, again, from existing data (e2).

Assessment of pooled effects and heterogeneity

A random-effects synthesis makes the assumption that individual studies are estimating different effects, which are assumed to have a normal distribution. For our umbrella review, we performed a random-effects meta-analysis to estimate the mean of this distribution of effects across different studies and the uncertainty about that mean (95% confidence interval [CI]). Cut-offs of one half, one, and two standard deviations of the response in the control group (taken from the largest included trials) were used to augment all forest plots with contours of effect magnitude.

We assessed heterogeneity between studies by calculating both the variance among effect sizes (tau^2) and the I^2 metric of inconsistency, which reflects the proportion of total variability in the results explained by heterogeneity and not by chance (e5). The I^2 metric ranges between 0% and 100%, and is the ratio of variance between studies over the sum of variances within and between studies. We also assessed descriptively whether heterogeneity would influence the direction or only magnitude of effects (i.e. if pooled studies lay on both sides or on only one side of the forest plot, respectively) (e6). Finally, we calculated the 95% prediction interval (PrI) for the pooled random-effects estimates, which further accounts for heterogeneity between studies and indicates the uncertainty for the effect that would be expected in a new study with a similar design/setting examining that same association (e7).

Predefined mixed-effects subgroup analyses and random-effects meta-regressions were performed for the following factors: baseline patient characteristics (including mean age, ratio of male patients, mean AHI, mean BMI, and sample size), follow-up time, % of maximum protrusion in the construction of intraoral appliances (IOA), appliance category (custom IOA based on impressions, pre-fabricated IOA, tongue suction IOA), and appliance type (1- or 2-piece). Sensitivity analyses were performed to assess any systematic differences according to study design (parallel or crossover) and data calculations done for this umbrella review.

Assessment of small-study effects

We examined whether there were indications pointing to small-study effects—that is, if small studies tended to give higher estimates than large studies. Small-study effects can indicate publication bias or other reporting biases, but they may also reflect genuine heterogeneity, chance, or other reasons for differences between small and large studies (e8). We used the regression asymmetry test proposed by Egger et al. (e9) to investigate funnel plot asymmetry in meta-analyses of at least 10 studies (e8).

Epidemiological criteria for the robustness of associations

We further assessed which random-effects meta-analyses with statistically significant estimates fulfilled the following epidemiological criteria for robust associations:

- $p<0.001$, a threshold that has been suggested to reduce the number of false-positive findings (e10)
- Associations based on adequate sample size (>500 patients)
- Associations without large heterogeneity between studies ($I^2<75\%$) potentially affecting the direction of estimates
- Their 95% PrI excluded the null value

- No evidence of small-study effects (according to the Egger's test).

All p-values were two-sided, while statistical significance was set at 5% for all tests, except for heterogeneity and Egger's tests (10%). Although multiple p-values are reported in this umbrella review, the significance level was not adjusted, as we aimed to summarize the results of the included papers.

eBOX 1

Eligibility criteria for selecting systematic reviews and primary studies

1. Criteria for the inclusion of systematic reviews (with or without meta-analysis)

Inclusion criteria

- At least one database was systematically searched and
- The study follows a systematic methodology (at least rudimentarily) using methods such as:
  - Methodological quality assessment of the included studies using any tool or
  - Conduct of a meta-analysis or
  - Duplicate study selection or data extraction by two independent reviewers.

Exclusion criteria

- Systematic reviews of animal studies, narrative reviews, and clinical practice guidelines merely based on a literature search

2. Criteria for selecting primary studies included in the systematic reviews

Inclusion criteria

- Patients with an a priori diagnosis of OSA (AHI ≥ 5 or RDI ≥ 5 for adults and AHI ≥ 1 for children) of any age or sex
- IOA, RME, SARME, or MMA to alleviate / treat OSA
- Direct comparisons between two or more interventions or between patients receiving the intervention and untreated / placebo matched controls
- Randomized controlled trials or prospective non-randomized clinical trials of parallel or crossover design
- Any clinical setting
- Primary outcome: AHI measured with polysomnography before and after the intervention
- Secondary outcomes measured before and after the intervention: RDI, oximetry indices, sleep efficiency, REM sleep latency, and ESS

Exclusion criteria

- Studies reporting on patients suffering from conditions other than OSA
- Non-clinical studies, retrospective clinical studies, case series (less than 10 patients), and case reports

OSA, obstructive sleep apnea; AHI, apnea hypopnea index; RDI, respiratory disturbance index, IOA, intraoral appliance; RME, rapid maxillary expansion; SARME, surgically assisted rapid maxillary expansion; MMA, maxillomandibular advancement; REM, rapid eye movement; ESS, Epworth Sleepiness Scale

eBOX 2

Characteristics of the included systematic reviews

- Twenty eight reviews were published in scientific journals, while one was published as a Health Technology Assessment.
- All reviews were published in English between 1996 and 2016 and each searched between one and nine literature databases.
- Ten (34%) reviews included only RCTs, 7 (24%) included both RCTs and non-RCTs, and the remaining 12 (41%) only included non-RCTs.
- The majority of them (16 reviews; 55%) assessed intraoral appliances, 9 (31%) assessed surgical maxillomandibular advancement, 3 (10%) assessed maxillary expansion, and one assessed more than one intervention.
- Almost all of the reviews (27 reviews; 93%) reported on the primary outcome AHI, 14 (48%) reported on ESS, and 15 (52%) reported on oxygen saturation indices.
- From the included systematic reviews, 12 (41%) had no conflicts of interest, 9 (31%) declared non-profit support, 2 (7%) involved company support, and 6 (21%) did not declare any status.
- At the time this umbrella review was conducted, 4 included reviews had not been cited, while the rest gathered in total 2980 citations in Google Scholar (median=21; range=1–1016)

AHI, Apnoe-Hypopnoe-Index; ESS, Epworth Sleepiness Scale

eBOX 3

Risk of bias and methodological adequacy of the included systematic reviews

- Out of the 29 included systematic reviews, 23 (79%) assessed the risk of bias in the included primary studies; 7 (24%) of these used the Cochrane Collaboration's risk of bias tool.
- The quality of evidence (strength of recommendations) from the performed meta-analyses was assessed with the GRADE approach in a mere 7 out of 29 reviews (24%) and with other approaches in another 2 reviews (7%). The strength of recommendations of the included reviews ranged from very low to high.
- The AMSTAR scores for the included reviews ranged from 1 to 9 out of 11 possible points, with a mean score of 5 (excluding non-applicable ratings) and a standard deviation of 2, with no review scoring full points.
- The main shortcomings were a lack of a priori design (in 22 [76%] of the reviews), incomplete reporting of included / excluded studies (in 24 [83%] of the reviews), absence of grey literature searches (in 21 [72%] of the reviews), and missing statements for possible conflicts of interest (in all of the reviews).

eBOX 4

List of included primary studies

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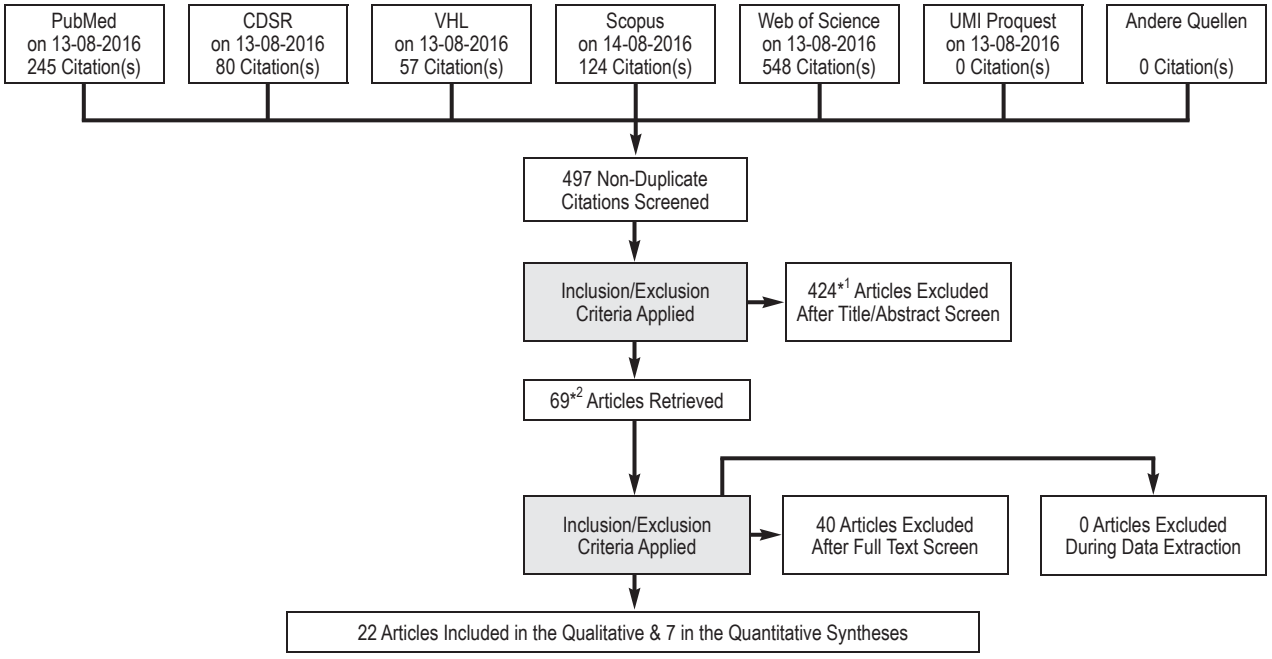
20 Villa MP, Bernkopf E, Pagani J, Broia V, Montesano M, Ronchetti R. Randomized controlled study of an oral jaw-positioning appliance for the treatment of obstructive sleep apnea in children with malocclusion. Am J Respir Crit Care Med. 2002 Jan 1; 165(1) :123–7.

eFIGURE



Flow diagram for the selection of included studies

CDSR, Cochrane Database of Systematic Reviews; VHL, Virtual Health Library.

*1 Three abstracts could not be found; *2 One full text could not be found

eTABLE 1

Identification of studies: databases, dates, search strategies, and hits

Database and date searched	Search query	Hits per query	Hits per database
PubMed www.ncbi.nlm.nih.gov/pubmed/advanced, am 13.08.2016	((((appliance OR device OR splint*)) AND (mandib* OR "lower jaw")) AND ("obstructive sleep apnoea" OR "obstructive sleep apnea" OR OSA OR apnea OR apnoea OR snor* OR breath* OR respir* OR hypopnea OR sleep*)) Filters: Review	132	245
	((((maxilla* OR palat*)) AND expansion) AND ("obstructive sleep apnoea" OR "obstructive sleep apnea" OR OSA OR apnea OR apnoea OR snor* OR breath* OR respir* OR hypopnea OR sleep*)) Filters: Review	43	
	((((("maxillomandibular advancement" OR osteotomy OR BSSO OR "bilateral sagittal split osteotomy" OR "mandibular advancement" OR "Le Fort" OR "maxillary advancement"))) AND (("obstructive sleep apnoea" OR "obstructive sleep apnea" OR OSA OR apnea OR apnoea OR snor* OR breath* OR respir* OR hypopnea OR sleep*))) Filters: Meta-Analysis; Systematic Reviews	70	
Cochrane Database of Systematic Reviews http://onlinelibrary.wiley.com/cochranelibrary/search, am 13.08.2016	(appliance OR device or splint*) and (mandib* OR "lower jaw") and ("obstructive sleep apnoea" OR "obstructive sleep apnea" OR OSA or apnea OR apnoea OR snor* OR breath* OR respir* OR hypopnea OR sleep*) in Cochrane Reviews (Search all text)	46	80
	("maxillary expansion" OR "palatal expansion") and ("obstructive sleep apnoea" OR "obstructive sleep apnea" OR OSA OR apnea OR apnoea OR snor* OR breath* OR respir* OR hypopnea OR sleep*) in Cochrane Reviews (Search all text)	6	
	("maxillomandibular advancement" OR osteotomy OR BSSO or "bilateral sagittal split osteotomy" OR "mandibular advancement" OR "Le Fort" or "maxillary advancement") and ("obstructive sleep apnoea" OR "obstructive sleep apnea" OR OSA or apnea or apnoea or snor* OR breath* OR respir* OR hypopnea OR sleep*) in Cochrane Reviews (Search all text)	28	
Virtual Health Library http://pesquisa.bvsalud.org/portal/advanced/?lang=en, am 13.08.2016	(tw:(appliance OR device OR splint*)) AND (tw:(mandib* OR "lower jaw")) AND (tw:("obstructive sleep apnoea" OR "obstructive sleep apnea" OR OSA OR apnea OR apnoea OR snor* OR breath* OR respir* OR hypopnea OR sleep*)) AND (tw:("systematic review" OR "meta-analysis")) in Title, abstract, subject	16	57
	(tw:("maxillary expansion" OR "palatal expansion")) AND (tw:("obstructive sleep apnoea" OR "obstructive sleep apnea" OR OSA OR apnea OR apnoea OR snor* OR breath* OR respir* OR hypopnea OR sleep*)) AND (tw:("systematic review" OR "meta-analysis")) in Title, abstract, subject	9	
	(tw:("maxillomandibular advancement" OR osteotomy OR BSSO OR "bilateral sagittal split osteotomy" OR "mandibular advancement" OR "Le Fort" OR "maxillary advancement")) AND (tw:("obstructive sleep apnoea" OR "obstructive sleep apnea" OR OSA OR apnea OR apnoea OR snor* OR breath* OR respir* OR hypopnea OR sleep*)) AND (tw:("systematic review" OR "meta-analysis")) in Title, abstract, subject	32	
Scopus www.scopus.com/search/, am 14.08.2016	(TITLE-ABS-KEY ("maxillomandibular advancement" OR osteotomy OR bsso OR "bilateral sagittal split osteotomy" OR "mandibular advancement" OR "Le Fort" OR "maxillary advancement") AND TITLE-ABS-KEY ("obstructive sleep apnoea" OR "obstructive sleep apnea" OR osa OR apnea OR apnoea OR snor* OR breath* OR respir* OR hypopnea OR sleep*) AND TITLE-ABS-KEY ("systematic review" OR "meta-analysis"))	61	124
	(TITLE-ABS-KEY (((((appliance OR device OR splint*)) AND (mandib* OR "lower jaw")) AND ("obstructive sleep apnoea" OR "obstructive sleep apnea" OR osa OR apnea OR apnoea OR snor* OR breath* OR respir* OR hypopnea OR sleep*))) AND TITLE-ABS-KEY ("systematic review" OR "meta-analysis"))	53	
	(TITLE-ABS-KEY (((((maxilla* OR palat*)) AND expansion) AND ("obstructive sleep apnoea" OR "obstructive sleep apnea" OR osa OR apnea OR apnoea OR snor* OR breath* OR respir* OR hypopnea OR sleep*))) AND TITLE-ABS-KEY ("systematic review" OR "meta-analysis"))	10	
Web of Science http://apps.webofknowledge.com/, am 13.08.2016	TOPIC: (appliance OR device OR splint*) AND TOPIC: (mandib* OR "lower jaw") AND TOPIC: ("obstructive sleep apnoea" OR "obstructive sleep apnea" OR OSA OR apnea OR apnoea OR snor* OR breath* OR respir* OR hypopnea OR sleep*) Refined by: DOCUMENT TYPES: (REVIEW) All Databases	208	548
	TOPIC: ("maxillary expansion" OR "palatal expansion") AND TOPIC: ("obstructive sleep apnoea" OR "obstructive sleep apnea" OR OSA OR apnea OR apnoea OR snor* OR breath* OR respir* OR hypopnea OR sleep*) Refined by: DOCUMENT TYPES: (REVIEW) All Databases	64	
	TOPIC: ("maxillomandibular advancement" OR osteotomy OR BSSO OR "bilateral sagittal split osteotomy" OR "mandibular advancement" OR "Le Fort" OR "maxillary advancement") AND TOPIC: ("obstructive sleep apnoea" OR "obstructive sleep apnea" OR OSA OR apnea OR apnoea OR snor* OR breath* OR respir* OR hypopnea OR sleep*) Refined by: DOCUMENT TYPES: (REVIEW) All Databases	276	

Database and date searched	Search query	Hits per query	Hits per database
UMI Proquest http://search.proquest.com/advanced/reset?accountid=13478, am 13.08.2016	(appliance OR device OR splint*) AND (mandib* OR "lower jaw") AND ("obstructive sleep apnoea" OR "obstructive sleep apnea" OR OSA OR apnea OR apnoea OR snor* OR breath* OR respir* OR hypopnea OR sleep*) in Dissertations & Theses / Anywhere	0	0
	("maxillary expansion" OR "palatal expansion") AND ("obstructive sleep apnoea" OR "obstructive sleep apnea" OR OSA OR apnea OR apnoea OR snor* OR breath* OR respir* OR hypopnea OR sleep*) in Dissertations & Theses / Anywhere	0	
	("maxillomandibular advancement" OR osteotomy OR BSSO OR "bilateral sagittal split osteotomy" OR "mandibular advancement" OR "Le Fort" OR "maxillary advancement") AND ("obstructive sleep apnoea" OR "obstructive sleep apnea" OR OSA OR apnea OR apnoea OR snor* OR breath* OR respir* OR hypopnea OR sleep*) in Dissertations & Theses / Anywhere	0	
Sum			1054

eTABLE 3

Methodological quality of included systematic reviews

Citation	1. Was an 'a priori' design provided?	2. Was there duplicate study selection and data extraction by two independent reviewers?	3. Was a comprehensive and systematic literature search performed?	4. Were unpublished study data as well as grey literature appropriately considered?	5. Was a list of studies (included and excluded) provided?	6. Were the characteristics (patient characteristics, interventions, outcomes) of the included studies provided?	7. Was the scientific quality of the included studies assessed and documented?	8. Was the scientific quality of the included studies used appropriately in formulating conclusions?	9. Were the methods appropriate that were used to combine the findings of studies?	10. Was the likelihood of publication bias assessed?	11. Was the conflict of interest included?
Abdullatif (2016) (e11)	No	No	Yes	Yes	No	Yes	Yes	No	Yes	Yes	No
Ahrens (2011) (e12)	No	Yes	Yes	No	No	No *2	No	No	NA	No	No
Bartolucci (2016) (e13)	No	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	No
Bratton (2015) (e14)	Yes	Yes	Yes	No	No	Yes	Yes	No	Yes	Yes	No
Bridgman (2000) (e15)	No	Yes	Yes	Yes	No	No	Yes	Yes	NA	No	No
Caldas (2009) (e16)	No	Yes	No	No	No	Yes	Yes	No	NA	No	No
Camacho (2015) (e17)	No	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	No
Caples (2010) (e18)	Yes	Yes	Yes	No	No	Yes	Yes	Yes	No	No	No
Carvalho (2007, 2016) (e19, e20)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	NA	Yes	No
Health Quality Ontario (2009) (e21)	No	No	Yes	No	No	Yes	Yes	Yes	Yes	No	No
Hoekema (2004) (e22)	No	No	Yes	Yes	No	Yes	Yes	Yes	No	No	No
Holty (2010) (e23)	No	Yes	No	No	No	Yes	No	No	No	No	No
Hsieh and Liao (2013) (e24)	No	Yes	No	No	No	Yes	Yes	Yes	NA	No	No
Huynh (2016) (e25)	Yes	Yes	Yes	No	Yes	Yes	No *3	Yes	No	No	No
Knudsen (2015) (e26)	No	No	Yes	No	No	No	No	No	Yes	Yes	No
Li (2013) (e27)	Yes	Yes	Yes	No	No	Yes	Yes	No	Yes	Yes	No

Citation	1. Was an 'a priori' design provided?	2. Was there duplicate study selection and data extraction by two independent reviewers?	3. Was a comprehensive and systematic literature search performed?	4. Were unpublished study data as well as grey literature appropriately considered?	5. Was a list of studies (included and excluded) provided?	6. Were the characteristics (patient characteristics, interventions, outcomes) of the included studies provided?	7. Was the scientific quality of the included studies assessed and documented?	8. Was the scientific quality of the included studies used appropriately in formulating conclusions?	9. Were the methods appropriate that were used to combine the findings of studies?	10. Was the likelihood of publication bias assessed?	11. Was the conflict of interest included?
Lim (2004) (e28)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No	No
Machado-Júnior (2016) (e29)	No	No	No	No	No	Yes	No	No	No	No	No
Marcus (2012) (e30)	No	No	Yes	No	No	No	Yes	Yes	n.a.	No	No
Marklund (2012) (e31)	No	No	Yes	No	No	Yes	Yes	Yes	n.a.	No	No
Nazarali (2015) (e32)	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
Okuno (2014) (e33)	No	Yes	Yes	No	No	Yes	Yes	No	Yes	Yes	No
Pirklbauer (2011) (e34)	No	No	No	No	No	Yes	Yes	No	n.a.	No	No
Ramar (2015) (e35)	No	No	Yes	No	No	No	Yes	Yes	Yes	Yes	No
Serra-Torres (2016) (e36)	No	No	Yes	No	No	Yes	Yes	No	n.a.	No	No
Sharples (2016) (e37)	No	Yes	Yes	No	No	No	Yes	No	Yes	Yes	No
Sher (1996) (e38) *1	Yes	Yes	No	No	No	No	No	No	n.a.	No	No
Zaghi (2016) (e39)	No	Yes	Yes	No	No	No	Yes	No	Yes	No *4	No
Zhu (2015) (e40)	No	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	No

NA, not applicable.
*1 Data extracted only on MMA
*2 Dead link
*3 Inappropriate tool
*4 Funnel-like plot provided, but no statistical confirmation

eTABLE 4

Overall results for the comparison of intraoral appliances vs placebo on the AHI

	Data	Trials	Effect	95% CI	p	95% PrI	τ^2	I^2 (%)
Meta-analysis	MD	12	–11.69	[–15.38; –8.01]	<0.001	–22.55; –0.85	20.15	93.6
Factor	**Data**	**Trials**	**Effect**	**95% CI**	**p**		**τ^2**	**I^2 (%)**
Follow-up (months)	Coefficient	11	0.25	[–0.24; 0.75]	0.273		21.23	94.7
	Constant		–14.40	[–21.20; –7.61]	0.001			
% of maximum protrusion	Coefficient	8	0.03	[–0.42; 0.48]	0.870		34.21	96.3
	Constant		–14.18	[–48.70; 20.34]	0.354			
Appliance type (thermoplastic vs impression-based)	Coefficient	13	6.25	[–3.73; 16.24]	0.196		17.12	89.4
	Constant		–12.17	[–15.68; 8.66]	<0.001			
Appliance type (1- or 2-piece)	Coefficient	9	–0.09	[–11.25; 11.08]	0.986		15.79	87.9
	Constant		–14.24	[–24.81; –4.30]	0.012			
Baseline-BMI (kg/m^2)	Coefficient	12	1.94	[–0.84; 4.72]	0.152		17.42	88.7
	Constant		–68.59	[–150.39; 13.21]	0.091			
Baseline AHI (events/hour)	Coefficient	11	–0.53	[–0.72; –0.34]	<0.001		2.84	46.3
	Constant		1.17	[–3.64; 5.99]	0.595			
Baseline age (years)	Coefficient	12	0.44	[–1.05; 1.93]	0.524		21.46	91.3
	Constant		–33.59	[–107.42; 40.25]	0.335			
Ratio of male patients	Coefficient	12	–28.65	[–78.34; 21.05]	0.228		18.8	93.7
	Constant		10.39	[–28.05; 48.82]	0.561			
Total sample	Coefficient	12	0.14	[0.04; 0.24]	0.010		9.78	73.7
	Constant		–19.13	[–25.29; –12.98]	<0.001			
Study design (crossover or parallel)	Coefficient	12	–0.52	[–8.85; 7.81]	0.892		22.5	94.2
	Constant		–11.38	[–18.25; 4.51]	0.004			
Data type 1	Coefficient	12	–1.20	[–10.98; 8.58]	0.790		22.39	94.2
	Constant		–11.49	[–15.81; –7.17]	<0.001			
Data type 2	Coefficient	12	8.07	[–1.72; 17.86]	0.096		15.9	89.2
	Constant		–12.77	[–16.47; –9.07]	<0.001			
Data type 1	Coefficient	12	0.22	[–9.36; 9.79]	0.274		18.15	90.2
Data type 2	Coefficient		8.12	[–2.63; 18.88]				
	Constant		–12.82	[–17.25; –8.39	<0.001			
	Data	**Trials**	**Effect**	**95% CI**	**p**			
Reporting bias (Egger's test)	Coefficient	12	–1.24	[–5.35; 2.87]	0.516			

CI, confidence interval; PrI, predictive interval; MD, mean difference; BMI, body mass index; Data type 1, origin of data used in the analysis 1 (increment calculated from parallel or cross-over trials); Data type 2, origin of data used in the analysis 2 (increment calculated from final values of cross-over trials)

eTABLE 5

Overall results for the comparison of intraoral appliances vs placebo on minimum oxygen saturation

	Data	Trials	Effect	95% CI	p	95% PrI	τ^2	I^2 (%)
Meta-analysis	MD	6	3.33	[1.38; 5.28]	0.007	–1.62; 8.28	2.19	96.8
Factor	**Data**	**Trials**	**Effect**	**95% CI**	**p**		**τ^2**	**I^2 (%)**
Follow-up (months)	Coefficient	5	–0.37	[–0.61; –0.14]	0.015		0.26	45.6
	Constant		7.20	[4.69; 9.70]	0.003			
% of maximum protrusion	Coefficient	NA						
	Constant							
Appliance type (1- or 2-piece)	Coefficient	5	2.19	[–13.13; 17.51]	0.680		3.22	92.0
	Constant		1.50	[–38.15; 57.79]	0.770			
Baseline BMI (kg/m^2)	Coefficient	6	–0.22	[–1.88; 1.43]	0.725		2.70	92.0
	Constant		9.82	[–38.15; 57.79]	0.600			
Baseline AHI (events/hour)		NA						
Baseline age (years)	Coefficient	6	–0.27	[–1.14; 0.60]	0.129		1.35	94.9
	Constant		16.42	[–25.56; 58.39]	0.200			
Ratio of male patients	Coefficient	6	22.38	[–10.19; 54.96]	0.129		1.35	94.9
	Constant		–14.03	[–39.43; 11.37]	0.200			
Total sample	Coefficient	6	–0.05	[–0.11; 0.00]	0.060		0.90	51.5
	Constant		6.48	[2.91; 10.05]	0.007			
Study design (crossover or parallel)	Coefficient	6	1.82	[–3.34; 6.97]	0.383		2.21	97.4
	Constant		1.90	[–2.67; 6.47]	0.313			
Data type 1	Coefficient	NA						
	Constant							
Data type 2	Coefficient	6	–1.87	[–14.97; 11.22]	0.712		2.69	97.4
	Constant		3.37	[1.04; 5.70]	0.016			
Data type 1	Coefficient	NA						
Data type 2	Coefficient							
	Constant							
	Data	**Trials**	**Effect**	**95% CI**	**p**			
Reporting bias (Egger's test)	Coefficient	NA						

CI, confidence interval; PrI, predictive interval; MD, mean difference; NA, not applicable; BMI, body mass index; AHI, apnea hypopnea index; Data type 1, origin of data used in the analysis 1 (increment calculated from parallel or cross-over trials); Data type 2, origin of data used in the analysis 2 (increment calculated from final values of cross-over trials).

eTABLE 6

Overall results for the comparison of intraoral appliances vs placebo on the Epworth Sleepiness Scale

	Data	Trials	Effect	95% CI	p	95% PrI	τ^2	I^2 (%)
Meta-analysis	MD	11	–1.18	[–2.38; 0.03]	0.055	–4.76; 2.40	2.12	60.6
Factor	**Data**	**Trials**	**Effect**	**95% CI**	**p**		**τ^2**	**I^2 (%)**
Follow-up (months)	Coefficient	10	0.04	[–0.21; 0.29]	0.716		3.40	67.2
	Constant		–1.56	[–3.95; 0.83]	0.170			
% of maximum protrusion	Coefficient	7	–0.00	[–0.13; 0.12]	0.950		3.36	66.4
	Constant		–1.48	[–10.38; 7.42]	0.686			
Appliance type (thermoplastic or tongue suction versus impression-based)	Coefficient (thermoplast)	10	–0.83	[–4.38; 2.72]	0.430		2.23	52.4
	Coefficient (tongue suction)		2.22	[–2.34; 6.78]				
	Constant		–1.62	[–3.31; 0.08]	0.059			
Appliance type (1- or 2-piece)	Coefficient	8	1.57	[–2.94; 6.07]	0.428			
	Constant		–1.87	[–4.39; 0.65]	0.120			
Baseline BMI (kg/m^2)	Coefficient	11	–0.21	[–1.30; 0.88]	0.671		2.60	56.5
	Constant		5.04	[–27.15; 37.23]	0.731			
Baseline AHI (events/hour)	Coefficient	9	–0.03	[–0.16; 0.10]	0.590		2.60	56.5
	Constant		–0.50	[–3.89; 2.88]	0.735			
Baseline age (years)	Coefficient	11	–0.28	[–0.65; 0.09]	0.119		1.29	40.9
	Constant		12.44	[–5.41; 30.29]	0.149			
Ratio of male patients	Coefficient	11	–15.22	[–33.47; 3.02]	0.092		1.11	60.1
	Constant		10.78	[–3.50; 25.05]	0.122			
Total sample	Coefficient	11	0.01	[–0.05; 0.06]	0.839		2.70	58.3
	Constant		–1.47	[–4.57; 1.63]	0.312			
Study design (crossover or parallel)	Coefficient	11	1.87	[–0.76; 4.50]	0.141			
	Constant		–2.63	[–4.97; –0.28]	0.032			
Data type 1	Coefficient	11	–1.87	[–4.50; 0.76]	0.141		1.42	60.3
	Constant		–0.75	[–1.93; 0.43]	0.185			
Data type 2	Coefficient	11	–0.93	[–4.88; 3.03]	0.609		2.55	48.2
	Constant		–1.08	[–2.49; 0.32]	0.115			
Data type 1	Coefficient	11	–2.12	[–4.80; 0.55]	0.197		1.27	41.6
Data type 2	Coefficient		–1.52	[–4.53; 1.49]				
	Constant		–0.49	[–1.76; 0.79]	0.405			
	Data	**Trials**	**Effect**	**95% CI**	**p**			
Reporting bias (Egger's test)	Coefficient	11	–0.26	[–2.08; 1.56]	0.752			

CI, confidence interval; PrI, predictive interval; BMI, body mass index; AHI, apnea hypopnea index; Data type 1, origin of data used in the analysis 1 (increment calculated from parallel or cross-over trials); Data type 2, origin of data used in the analysis 2 (increment calculated from final values of cross-over trials).

eTable 2: Selection of systematic reviews

Nr.	Citation	Exclusion based on	Reason
1	Aiello KD, Caughey WG, Nelluri B, Sharma A, Mookadam F & Mookadam M (2016): Effect of exercise training on sleep apnea: A systematic review and meta-analysis. Respiratory Medicine 116: 85–92.	title	Not relevant
2	Alessandri-Bonetti G, Ippolito DR, Bartolucci ML, D'Antò V & Incerti-Parenti S (2015): Cephalometric predictors of treatment outcome with mandibular advancement devices in adult patients with obstructive sleep apnea: a systematic review. Korean J Orthod 45: 308–321.	title	Not relevant
3	Annapurna K, Suganya S, Vasanth R & Kumar PR (2014): Prosthodontic approach to treat obstructive sleep apnea. Annals of medical and health sciences research 4: 481–6.	title	Not relevant
4	Atkeson A, Yeh SY, Malhotra A & Jelic S (2009): Endothelial Function in Obstructive Sleep Apnea. Progress in Cardiovascular Diseases 51: 351–362.	title	Not relevant
5	Attanasio R (1997): An overview of bruxism and its management. Dent Clin North Am 41: 229–241.	title	Not relevant
6	Bacher M, Linz A, Buchenau W, Arand J, Krimmel M & Poets C (2010): Treatment of Infants with Pierre Robin Sequence. Laryngo-Rhino-Otologie 89: 621–627.	title	Not relevant
7	Bagnall A-M, Jones L, Duffy S & Riemsma RP (2008): Spinal fixation surgery for acute traumatic spinal cord injury. Cochrane Database of Systematic Reviews. John Wiley & Sons, Ltd.	title	Not relevant
8	Bellamy N, Campbell J, Welch V, Gee TL, Bourne R & Wells GA (2006): Viscosupplementation for the treatment of osteoarthritis of the knee. Cochrane Database of Systematic Reviews. John Wiley & Sons, Ltd.	title	Not relevant
9	Bennett MH, Feldmeier J, Hampson NB, Smee R & Milross C (2016): Hyperbaric oxygen therapy for late radiation tissue injury. Cochrane Database of Systematic Reviews. John Wiley & Sons, Ltd.	title	Not relevant
10	Benson D, Klain M, Braslow A, *et al.*. (1996): Future directions for resuscitation research .1. Advanced airway control measures. Resuscitation 32: 51–62.	title	Not relevant
11	Benumof JL (1991): Management of the difficult adult airway. With special emphasis on awake tracheal intubation. Anesthesiology 75: 1087–1110.	title	Not relevant
12	Bezak BJ, Arce KA, Jacob A & Van Ess J (2016): Orthognathic Surgery in Patients With Congenital Myopathies and Congenital Muscular Dystrophies: Case Series and Review of the Literature. Journal of Oral and Maxillofacial Surgery 74: 601–609.	title	Not relevant
13	Bierma-Zeinstra SM, Brinks A, Verhagen AP, Van Rijn RM, Koes BW & Verhaar JA (2011): Interventions for lateral hip pain (tendinopathy or bursitis). Cochrane Database of Systematic Reviews. John Wiley & Sons, Ltd.	title	Not relevant
14	Bilkay U, Tiftikcioglu YO & Mezili C (2010): Management of Nasal Deformity in Osteogenesis Imperfecta. Journal of Craniofacial Surgery 21: 1465–1467.	title	Not relevant
15	Bloch KE (1997): Clinical significance of snoring. Schweizerische Medizinische Wochenschrift 127: 170–175.	title	Not relevant
16	Borrie FR, Bearn DR, Innes NP & Iheozor-Ejiofor Z (2015): Interventions for the cessation of non-nutritive sucking habits in children. Cochrane Database of Systematic Reviews. John Wiley & Sons, Ltd.	title	Not relevant
17	Brevi B, Di Blasio A, Di Blasio C, Piazza F, D'Ascanio L & Sesenna E (2015): Which cephalometric analysis for maxillo-mandibular surgery in patients with obstructive sleep apnoea syndrome? Acta Otorhinolaryngologica Italica 35: 332–337.	title	Not relevant
18	Brignardello-Petersen R, Carrasco-Labra A, Araya I, Yanine N, Cordova Jara L & Villanueva J (2015): Antibiotic prophylaxis for preventing infectious complications in orthognathic surgery. Cochrane Database of Systematic Reviews. John Wiley & Sons, Ltd.	title	Not relevant
19	Byrne M, Chan JCY & O'Broin E (2014): Perceptions and satisfaction of aesthetic outcome following secondary cleft rhinoplasty: evaluation by patients versus health professionals. J Craniomaxillofac Surg 42: 1062–1070.	title	Not relevant
20	Camacho M, Certal V, Abdullatif J, Zaghi S, Ruoff CM, Capasso R & Kushida CA (2015): Myofunctional Therapy to Treat Obstructive Sleep Apnea: A Systematic Review and Meta-analysis. Sleep 38: 669–675.	title	Not relevant
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