**Evidence Table - Oral Appliance Review**

| Author/ Citation | Question | Reviewer // Evidence Level | Study Design // Location (type) | Oral Appliance // Adjustable or Titratable // Titration | Selection Criteria Include (Exclude) // Sample Size // Rational // Gender // BMI // Hypopnea | Outcomes AHI // Min O2 Sat // ESS // Other // Adverse Events | Categorical Treatment // Snoring // Other // Predictors | Internal Bias // External Bias | Reviewer Comments | Study Conclusions |
|------------------|----------|-----------------------------|-------------------------------|------------------------------------------------|-------------------------------|------------------------------------------------|------------------------------------------------|-------------------------------|-------------------------------|-----------------------------|--------------------------|
| Barnes et al // 1,5 // WSN//1 | 1,5 // | RCT, comparison to placebo and to alternative treatment, crossover with CPAP, randomized treatment order, selected subjects, prospective// Sleep lab (full PSG, attended)// MRA, full, custom// Adjustable// Protocol defined: maximal comfortable protrusion, end-point criterion: maximal advance tolerated, advance measured: 10.3 mm (0.3) | OSA/severity, dental criteria (NS)/ NS/ 47.0 (0.9)/ 80% M// 31.1 (0.5)/ Referenced | Baseline AHI 21.3 ±1.3 (mean±SD); CPAP grp: post = 4.8 ±0.5, p=.001, .05 vs MRA; MRA grp: post = 4.8 ±0.5, p= .001; Placebo grp: post = 20.3 ±1.1, p=NS// Baseline Min SaO2: 86.7 ± 0.6 (mean±SD); CPAP grp: post = 91.9 ± 0.3 p=.001; .05 vs MRA; MRA grp: post = 87.8 ±0.4%, p= .001; Placebo grp: post = 95.4 ±0.6%, p=NS// Baseline ESS 10.7 ±0.4 (mean±SD); CPAP grp: post = 9.2 ±0.4, p= .001; MRA grp: post = 9.2 ±0.4, p= .001; Placebo grp: post mean= 10.2 ±0.4, p=NS// FOSQ-Baseline = 3.1 ±0.1 (mean±SD); CPAP grp: post =3.3 ±0.1, p= .001; MRA grp: post = 3.3 ±0.1, p= .001; Placebo grp: post mean= 3.3 ±0.1, p=.01. MWT- Baseline grp: =30.7 ±0.9 (mean±SD); CPAP grp: post = 30.0 ±0.9, p=NS; MRA grp: post = 29.6 ±0.9, p=NS; Placebo grp: 28.0 ±0.9, p=NS// NS | NS/ MRA, Success- AHI<10 grp: 49.1% success; AHI<15, no sx success/ NS | Patient selection: no, confounding factors: no directional dropout of bias, crossover bias: randomized// Population generalized: to OSA of mild-moderate severity (AHI 30-) | In a placebo-controlled RCT, efficacy is CPAP>MRA=placebo; sleepiness, CPAP>MRA=placebo; QoL, CPAP=MRA=placebo; and neurobehavioral tests no change |
| Bloch, et al // 1,6// JT//1 | 1,6// | Case series with crossover, comparison to baseline and alternate therapy, randomized treatment order // Sleep lab (full PSG, attended) // Herbst, Monobloc, full, custom// Adjustable// Protocol defined: yes, end point: subjective success, anterior opening measured: yes | Snoring + OSA (AH>5), adequate dentition (dental criteria- dental disease, sleep disorders)// Sample size not justified // 50.5 ± 1.5 // 24M, 1F // 27.4±0.6 // <25% baseline calibrated- Respitrace sum signal | Herbst grp: pre AHIAHI= 22.6± 3.1 (mean±SD), post = 8.7±1.5, p<.05; Monobloc grp: pre = 22.6±3.1, post = 7.9±1.6, p<.05 // NS // Herbst grp: pre ESS = 13.5, (mean±SD), post = 9.0, p<.05; Monobloc grp: pre = 13.5, post = 9.0, p<.05 // Arousal index: Herbst grp: pre mean= 41.0±3.7, post mean= 30.9±3.6 p<.05; Monobloc grp: pre mean=41.0±3.7, post mean= 26.5±3.9, p<.05. Snoring index: Herbst grp: pre mean= 41.0±3.7, post mean= 32.5±4.6, p=.05; Monobloc grp: pre mean= 41.0±3.7, post mean= 21.4 ± 4.2, p<.05 // Minor-temp: TMJ pain 7/24, tooth pain 3/24 muscle pain 4/24, same incidence each MRA | Herbst grp: 53% success, Monobloc grp: 74% success, no significant difference; Preference- Herbst: 1/24, Monobloc: 15/24, p=.008// NS/ NS | Patient selection: CPAP-refusing OSA, variable severity// Population generalized: OSA refusing CPAP, intensity: mild-severe | Two oral appliances improve snoring and OSA to similar degrees, but the custom Monobloc is preferred to the Herbst OA |
| Engelman, et | Randomized | OSA/severity; MRA grp: pre mean=31 ± 26, | | | | | | | | | | |
controlled crossover, comparison to CPAP, consecutive subjects, prospective, PSG scorer blinded; Sleep lab initially, baseline PSG, f/u home (respiratory monitoring, unattended); MRA 1 custom, full; MRA 2 custom, partial; Yes; Crossover after 2 months on each Rx, protocol defined: set at 80% max mandibular protrusion, anterior open measured; 2-4mm

AHI>4, age> 18 to 70, 2 or more symptoms include sleepiness-ESS >8 or sleepiness driving (dental criteria: <4 teeth either arch, other-plms, narcolepsy, major medical illness, shift work, living more than 50 miles from Edmonton)/N=48 allowed power of 99% to detect 1 SD difference between treatment scores// 46 ± 9 years (range 18-70)/48 finished-36 M, 12 F/28 ± 4 MRA, 31 ± 5 CPAP/NS postmean=15 ± 16, 52% decrease; CPAP grp: pre mean=31 ± 26, post mean=8 ± 6, 74% decrease, effect size CPAP vs MRA .45, p<.001/NS/ MRA grp: pre mean=14 ± 4, post mean=12 ± 5;CPAP grp: pre mean=14 ± 4, post mean=8 ± 5, effect size .57 CPAP vs MRA, p<.001// Performance-quality of life, FOSQ- MRA grp: post mean=13 ± 3; CPAP grp: post mean=14 ± 2, effect size .51 between CPAP & MRA,.001; Well being- SF 36- all 3 parameters better with CPAP than MRA, effect sizes .34 - .52 for the 3 parameters// NS// Minor/temporary; pain=33(69%); excess salivation=9(19%); poor retention=19(40%); sleep disturbance=12 (25%); CPAP mask problems=11 (23%), mask off during sleep 7 (15%), sleep disturbance=16 (33%), stuffy nose=8 (17%)

4 Ferguson, et al/1,25/1,3,4,5//WSN/1 Crossover with other appliance with CPAP// Sleep lab, home (PSG, attended)// MRA, full occlusal coverage,custom// Titratable// NS

OSA/severity, dental criteria/ (OSA/severity, dental criteria)/ NS/44 (10.6)/ NS/32 (8.2)/ 50% decrease in Respitrace (effort) MRA grp: pre mean=25.3(15.0), post mean=14.2(14.7), p <.005; CPAP grp: pre mean=23.5(16.5), post mean=4.0(2.2), p <.005 // MRA grp: pre mean=78.7(6.8), post mean=75.8(11.6); CPAP pre mean=76.8(9.1), post mean=87.7(2.4) // MRA grp: post mean=10.3(3.1), post mean=4.7(2.6), p <.005; CPAP grp: pre mean=11.0(3.8), post mean=5.1 (3.3), p <.05/NS/Minor/temporary; pain, sore teeth, jaw muscles, minor, temp; difficult chewing in AM, excessive salivation

MRA grp: 45%failed, CPAP grp: 0%failed// NS// NS Patient selection: yes, errors in ascertain: uncertain (home study)// Population generalized: gender not specified, intensity: mild to moderate OSA

OA is an effective treatment in some patients with mild to moderate OSA and is associated with greater satisfaction than CPAP

5 Ferguson, et al/25/1,4,5//KF-RC/1 Randomized cross-over with MRA and CPAP// Sleep lab (attended, PSG for Dx pre and post at home PSG unattended)//

OSA/severity-mild=moderate AHI (15-50), dental criteria - 10 teeth each arch, live in metro Vancouver MRA grp: pre mean=19.7±13.8, post mean=9.7±7.3, 51% decrease, p<0.005; CPAP grp: pre mean=17.6±13.2, post mean=3.6±1.7, 80% decrease, p<0.005// Lowest saturations-MRA grp: pre mean= MRA grp: 76% success; CPAP grp: 100%success// Treatment success = NS, NS, No crossover bias - tested for period and carryover effect, 2 week Randomized controlled cross-over follow-up - complete follow-up on 25 of 27 patients enrolled for the clinical data

CPAP more effective 62% vs 48% with criterion <10 and symptoms reduced. Side effects more common with CPAP: patient preference and patient
SnoreGuard partial occlusal, non-custom or pre-fabricated? // No // Protrusion 7mm, anterior opening 7mm (NS) // NS // 46.2±10.9 (25-72) // 24 M, 3 F // 30.4±4.8 (21-42) // ≥50% decrease effort // 83% ±7.4, post mean= 83.8% ±7.3, unchanged; CPAP grp: pre mean= 83% ±6, post mean= 88.7% ±2.5, 7.4% increase, p<0.05 // NS // Muscle pain with MRA mild and temp, 1 patient mod-sev; no TMJ; more side effects with CPAP // AHI<10 with improved symptoms - MRA 48% vs 62% for CPAP// ED50-MRA grp: 52% success; CPAP grp: 72% success. Satisfaction moderately - very satisfied p< 0.05 SG vs CPAP- SG grp: 68% success; CPAP grp: 62% success/NS // MRA grp: pre mean= AHI 27.1 ±15.3, post mean=12 ± 2, 55.6% decrease, p=significant; placebo grp: pre mean= AHI 27.1±15.3 post mean=25±2, 7.7% decrease, p=NS, MRA vs. Control p<0.001// MRA grp: pre mean= 86±6, post mean= 86±1, 0% change, p<0.001 MRA vs Control// MRA grp: pre mean= 11 ±5, postmean= 7±1, 36.3% decrease, p=significant; placebo grp: pre mean= 11±5, post mean= 9±1, 18% decrease, p<0.01, p<.0001 MRA vs placebo, (82% normal ESS in MRA vs 62% placebo, p<.01) // Arousal index- MRA grp: pre mean= 35±13.5, post mean= 35±13.5, 0% decrease. Partial resp (AHI down by 50% but<5)- MRA grp: 27% success; Placebo grp: 0% success. Treatment failure (AHI not down by 50% or >5)- MRA grp: 27 failure (37%) Grp Placebo 73 failure (100%)/NS // Patient selection: yes, confounding factors: no, crossover bias: no treatment by period interaction or period effects from MSLT, ESS, or PSG variables, errors in ascertain: good careful monitoring, loss to f/u: not a problem// Population generalized: yes, likely, intensity: good range of severity // More patients reported improved frequency & intensity of snoring with MRA, more patients reported improved sleep quality with MRA, more patients reported improved satisfaction with MRA, good snoring measurement objectively obtained, well done, thorough follow-up, no effect of placebo, large sample size // Large randomized placebo controlled study showed that MRA improve snoring, AHI and both subjective and objective sleepiness // 83% ±7.4, post mean= 83.8% ±7.3, unchanged; CPAP grp: pre mean= 83% ±6, post mean= 88.7% ±2.5, 7.4% increase, p<0.05 // NS // Muscle pain with MRA mild and temp, 1 patient mod-sev; no TMJ; more side effects with CPAP // AHI<10 with improved symptoms - MRA 48% vs 62% for CPAP// ED50-MRA grp: 52% success; CPAP grp: 72% success. Satisfaction moderately - very satisfied p< 0.05 SG vs CPAP- SG grp: 68% success; CPAP grp: 62% success/NS // MRA grp: pre mean= AHI 27.1 ±15.3, post mean=12 ± 2, 55.6% decrease, p=significant; placebo grp: pre mean= AHI 27.1±15.3 post mean=25±2, 7.7% decrease, p=NS, MRA vs. Control p<0.001// MRA grp: pre mean= 86±6, post mean= 86±1, 0% change, p<0.001 MRA vs Control// MRA grp: pre mean= 11 ±5, postmean= 7±1, 36.3% decrease, p=significant; placebo grp: pre mean= 11±5, post mean= 9±1, 18% decrease, p<0.01, p<.0001 MRA vs placebo, (82% normal ESS in MRA vs 62% placebo, p<.01) // Arousal index- MRA grp: pre mean= 35±13.5, post mean= 35±13.5, 0% decrease. Partial resp (AHI down by 50% but<5)- MRA grp: 27% success; Placebo grp: 0% success. Treatment failure (AHI not down by 50% or >5)- MRA grp: 27 failure (37%) Grp Placebo 73 failure (100%)/NS // Patient selection: yes, confounding factors: no, crossover bias: no treatment by period interaction or period effects from MSLT, ESS, or PSG variables, errors in ascertain: good careful monitoring, loss to f/u: not a problem// Population generalized: yes, likely, intensity: good range of severity // More patients reported improved frequency & intensity of snoring with MRA, more patients reported improved sleep quality with MRA, more patients reported improved satisfaction with MRA, good snoring measurement objectively obtained, well done, thorough follow-up, no effect of placebo, large sample size // Large randomized placebo controlled study showed that MRA improve snoring, AHI and both subjective and objective sleepiness // 83% ±7.4, post mean= 83.8% ±7.3, unchanged; CPAP grp: pre mean= 83% ±6, post mean= 88.7% ±2.5, 7.4% increase, p<0.05 // NS // Muscle pain with MRA mild and temp, 1 patient mod-sev; no TMJ; more side effects with CPAP // AHI<10 with improved symptoms - MRA 48% vs 62% for CPAP// ED50-MRA grp: 52% success; CPAP grp: 72% success. Satisfaction moderately - very satisfied p< 0.05 SG vs CPAP- SG grp: 68% success; CPAP grp: 62% success/NS // MRA grp: pre mean= AHI 27.1 ±15.3, post mean=12 ± 2, 55.6% decrease, p=significant; placebo grp: pre mean= AHI 27.1±15.3 post mean=25±2, 7.7% decrease, p=NS, MRA vs. Control p<0.001// MRA grp: pre mean= 86±6, post mean= 86±1, 0% change, p<0.001 MRA vs Control// MRA grp: pre mean= 11 ±5, postmean= 7±1, 36.3% decrease, p=significant; placebo grp: pre mean= 11±5, post mean= 9±1, 18% decrease, p<0.01, p<.0001 MRA vs placebo, (82% normal ESS in MRA vs 62% placebo, p<.01) // Arousal index- MRA grp: pre mean= 35±13.5, post mean= 35±13.5, 0% decrease. Partial resp (AHI down by 50% but<5)- MRA grp: 27% success; Placebo grp: 0% success. Treatment failure (AHI not down by 50% or >5)- MRA grp: 27 failure (37%) Grp Placebo 73 failure (100%)/NS // Patient selection: yes, confounding factors: no, crossover bias: no treatment by period interaction or period effects from MSLT, ESS, or PSG variables, errors in ascertain: good careful monitoring, loss to f/u: not a problem// Population generalized: yes, likely, intensity: good range of severity // More patients reported improved frequency & intensity of snoring with MRA, more patients reported improved sleep quality with MRA, more patients reported improved satisfaction with MRA, good snoring measurement objectively obtained, well done, thorough follow-up, no effect of placebo, large sample size // Large randomized placebo controlled study showed that MRA improve snoring, AHI and both subjective and objective sleepiness //
<table>
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<th>No</th>
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<td>7</td>
<td>Hans, et al //32/</td>
<td>RCT, comparison to alternative appliance, crossover with other appliance (device B to Device A), prospective/Home (unattended, respiratory monitoring only)</td>
<td>12 patients MRA, 12 patients modified MRA without advance, partial, prefabricated/Protocal defined: MRA (device A) set with incisors edge to edge, ~ 6 to 8 mm forward protrusion, 6 to 8 mm ant opening, Device B: no advancement and 1 mm ant opening.</td>
<td>MRA (10 subjects) grp: pre mean=35.6 ± 28.4, post mean=21.1 ± 21.4, p≤0.05; Device B (8 subjects) grp: pre mean=36.5 ± 43.7, post mean= 46.8 ± 46.9, p=NS; All MRA (17 subjects) grp: 42.4 ± 37.5, post mean= 29.7 ± 21.4, p&lt;0.05/NS/MRA (10 subjects) grp: pre mean=12.0 ± 3.9, post mean=8.2 ± 4.0, p≤0.05; Device B (8 subjects) grp: pre mean= 13.0 ± 4.5, post mean=12.5 ± 5.7, p=NS; All MRA (17 patients) grp: pre mean=12.9 ± 4, post mean=9.6 ± 4, p&lt;0.005/NS/NS</td>
<td>Snoring, no systemic disease (OSA/severity:AH1 &gt;30/hour (unless referred), dental criteria: edentulous subjects, age: minors, chronic disease, sed-hypn meds, pregnant women, prisoners, minors, mental disability, previous surgery for OSA, other sleep disorders, severe EDS/NS/</td>
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| 8 | Johnston, et al //106/ | RCT, comparison to placebo group/Home (unattended, Snoring, OSA/severity, dental criteria | MRA grp: pre mean=31.9 (21.2) all patients, post mean=22.9 (22.8), p=0.011 OA vs placebo; Placebo grp: | NS/NS/NS | Confounding factors: NS/NS/NS | Patient selection: yes, by sleep study | Not a bad study, small in numbers, but patients randomized to the groups, one appliance unlikely to be effective (Device B) due to absence of advancement of mandible and in that group most patients got worse, the MRA (Device A) was fairly effective even in severe patients. |
| RR/2 | respiratory monitoring | MRA/ No | (NS)/ Yes | 55.1 | 16 M, 4 F/ 31.6 | 50% reduction air flow | post mean=37.7 (24.9) // NS// MAA grp: pre mean=13.9(6.4) all patients, post mean= 11.6(6.7), p= NS OA vs placebo; Placebo grp: post mean=12.6(6.3)// ODI-MAA grp: pre mean=30.7(18.8) all patients, post mean=21.1 (19.8), p=.002; OA vs placebo- Placebo grp: post mean=21.2(18.2) | position determined a priori, not adjustment for effect// NS | cases |
| 9 | Mehta, et al//56// 1,2,4,6// KF-RC//2 | Random crossover placebo control trial | Sleep lab (full PSG, attend) | MRA, full, custom//Yes// Advanced to max tolerated protrusion over 19.7±8.8 weeks (range 5-40 wks) mean advance 7.5 ± 1.8 mm (78% of max protrusion), anterior opening 3-4 mm | Snoring, OSA/severity- AHI ≥ 10 per hr, ≥ 2 symptoms of OSA (dental criteria - edentulous, periodontal disease, exaggerated gag reflex, regular sedative use)// Sample size of 30 for power of 0.8 and p< 0.05 // 48 ± 9 (range 35-73)/ 19 M.5 F// 29.4 ± 3.1 (24.8-36.3)/ ≥50% reduction in airflow or thoracoabdominal movement, 10 sec + a desaturation ≥3% or arousal | Active grp: pre mean= AHI 26 ± 15, post mean= 14 ± 2, 46% decrease; Placebo grp: pre mean= 26 ± 19, post mean= 30 ± 2, 16% increase; p<0.001 between active and placebo grp at outcome// Active grp: pre mean= 88 ± 7, post mean= 91 ± 1, 3% increase; Placebo grp: post mean= 82 ± 9, post mean= 87 ± 1, 6% increase; p<0.001 between active and placebo grp at outcome// Active grp: pre mean= 10.1 ± 1.1, post mean= 3.9 ± 0.6, p<0.01; Placebo grp: NS// Snoring Frequency per hour- Active grp: post mean: 242 ± 28, 47% decrease;Placebo grp: post mean= 402 ± 29, p<0.005 between active and placebo grp at outcome. Snoring- mean snoring intensity, dB- Active grp: post mean= 49 ± 1; Placebo grp: 52 ± 1, p= 0.0001 between active and placebo grp at outcome. Snoring, max snoring intensity, dB- Active grp: post mean= 68 ± 1; Placebo grp: post mean= 70 ± 1, p=NS between active and placebo grp at outcome. Arousal index- Active grp: post mean= 27 ± 2, 34% drop; Placebo grp: post mean= 41± 2, p=0.0001 between active and placebo grp at outcome// Minor-temporary: pain, jaw discomfort 12.5%, excess salivation 50%, gum irritation 20%, mouth dryness 46%, tooth grinding 12.5% | Subjective reports - Active grp:70% success// Complete success: resolution of symptoms & AHI < 5 per hour; partial response; improved symptoms & AHI reduced by 50% but AHI staying over 5 per hour; Tx failure: ongoing symptoms &/or not reduced by 50%; Compliance failure, inability to use the tx. Complete grp: 37.5% success; Partial grp: 25% success; Failure grp: 37.5% fail; Sleep Quality- Active frp: 91% success; Placebo grp: NS??//Predictive equation for post Rx AHI: neck circumference- baseline AHI (high NC or high AHI - higher AHI post Rx) + 2 | Patient selection: yes, No, No Crossover bias, None, loss to fu: few dropouts and they were considered compliance failures// Population generalized: typical OSA patients, intensity: good severity range | Calculated time in supine sleep but did not analyze effect of supine on A+HI with MAS, NC at online data supplement, blinding not mentioned | Well-done randomized placebo controlled crossover study - 62% had complete, or partial response in patients with moderate to severe OSA |
10 Pitsis, et al//97// 1,2,6//WSN-RR//1
RCT, comparison to placebo group, compare to alternative treatment group// Sleep lab (PSG, attended)/ No/ MRA-4, 14mm opening, full occlusal coverage, custom// NS// Protocol defined: yes, advance measured: yes, anterior opening measured: yes
OSA severity: AHl>5, other-2 symptoms (OSA- sex: CSA, dent crit: edent, other-perio disease)// NS/50 yrs mean// 20M, 3F/ 31 mean/ NS/ NS
MRA-1 4mm opening grp: pre mean= 21, post mean= 8; MRA-2 14mm opening grp: pre mean= 87, post mean= 89; MRA- 2 14mm open grp: pre mean= 87, post mean= 88/ MRA-1 4mm open grp: pre mean= 18, post mean= 12; MRA-2 14mm open grp: pre mean= 18, post mean= 12// NS/ NS// TMJ: min-temp, jaw discomfort, other- min- temp: salivation, dry mouth, tooth grinding, gum irritation Complete success (no sx, AHl<5)- 4mm grp: 52% success, 14mm grp: 35% success; partial success (sx better, AHl<50%) initially)- 4mm grp: 22% success, 14mm grp: 26% success/ NS// NS
CPAP more effective. MRA not titrated. Sub-optimal result with MRA

11 Randerath, et al//X09// 1/1KF//2
RCT, comparison to alternative treatment group// Sleep lab (full PSG, attended)// MRA, activator, full occlusal coverage, custom// NS// Not well described, anterior opening measured: 12 mm
CPAP more effective,MRA not titrated. Sub-optimal result with ISAD// No/56.5 ± 10.2/16M,4F// NS// Reduction of ≥ 50% in airflow > 10 sec or reduced flow and effort with a 4% desat
MRA grp: pre mean=17.5 ± 7.7, post mean= 13.8 ± 11.1; CPAP grp: pre mean=17.5 ± 7.7, post mean=3.2 ± 2.9/ MRA grp: pre=83.6 ± 4.6, post=85.3 ± 3.1; CPAP grp: pre= 83.6 ± 4.6, post= 89 ± 3.4//NS//Arousal Index-MRA grp: pre=21.8 ± 9.9, post=17 ± 5.1; CPAP grp: pre=21.8 ± 9.9, post=14.1 ± 5.1; Snoring (snores per hour)- MRA grp: pre=54.5 ± 26hr, post=36.4 ± 17.7; CPAP grp: pre=54.5 ± 26, post=10.3 ± 5.0 // NS
NS/Success AHl < 10- ISAD- 30% success, 70% failed; CPAP- 100% success// No AHl, younger age, better result
Patient selection: yes, confounding factors: no, crossover bias: no, errors in ascertaining: no, loss to fu: no// Population generalized: yes, intensity;mild to moderate
CPAP more effective. MRA not titrated. Sub-optimal result with MRA

12 Rose, et al//107// 1/2,3//KF-RR//2
Randomized crossover with other appliance, prospective/ Both sleep lab, home (attended baseline PSG, unattended home, respiratory monitoring for fu)/ MRA: type A MRA-full, custom; MRA: type B MRA partial, custom// Both adjustable// Protocol defined: both appliances were set at 75% max protrusion, anterior opening: MRA-5mm, MRA appliance-10-12mm
Mild OSA, >10 healthy teeth per arch, refused CPAP//TMJ problems// No/ 56.5±5.2//22M, 4F/ 27.5±3.1/ Airflow reduced by ≥ 50% below baseline for at least 10 seconds
Type A MRA grp: pre mean= 16.0±4.4 post mean= 7.4±5.3, 53.8% decrease, p≤0.01/Type B MRA grp: pre mean=16.2±4.6 post mean= 5.5±3.3, 66% decrease, p≤0.01//Type A MRA grp: pre mean=89.1±3.2 post mean=90.1±4.8, 1% increase, p=NS/ Type B MRA grp: pre mean= 89.7±3.2 post mean= 89.1±3.2, 1% increase, p=NS/ Type A MRA grp: pre mean=91±0.8 post mean= 3.2±1.4, 65% decrease; Type B MRA grp: pre mean= 88±1.0 post mean= 3.4±2.7, 91% decrease, p=NS/ Daytime Sleepiness (VAS 1-10)- Type A MRA grp: pre mean= 7.2±1.7, post mean= 5.4±1.0, 25% decrease, p=NS/ Type B K grp: pre
NS/NS/NS
Patient selection: mild OSA, diagnosed in the sleep lab, confounding factors: randomized, crossover bias: not applicable, errors in ascertaining: subjects likely used the appliance, loss to fu: very high-large number failure to crossover
Well-done study in a thin older group of patients with mild OSA. Good comparison of 2 distinctive appliances. Trouble following the patients in the trial-not all clearly accounted for. The AHl was lower with the MRA appliance. No success rate given for reductions in AHl
Both appliances effective for mild OSA. Treatment outcome influenced by OA design

Long-term OA use produces dental movement, usually minor and asymptomatic. Bite opening of OA doesn't affect efficacy, but small opening more acceptable too
mean = 7.0 ± 1.5 post mean = 4.1 ± 0.7, 41% decrease, p = significant; Sleep quality (VAS 1-10)- Type A MRA grp: pre mean = 6.4 ± 1.8 post mean = 4.1 ± 1.4, 36% decrease p = significant; Type B MRA grp: pre mean = 6.2 ± 1.2 post mean = 4.5 ± 2.1, 27% decrease p = significant//Failure to tolerate: 1 patient, pain in jaw and/or TMJ: 2 patients; sev-d/c Rx, mild in 5/23, gag reflex: 1 patient d/c Rx, Other: failure to retain appliance in the mouth in 2 pts, xs salivation # not given

13 Tan, et al//102// 2.3/WSN,RR/1

Prosp, RCT, consecutive patients, crossover study of MRA to CPAP//Lab-PSG/full occlusal coverage//Single position appliance set at 75% of max protrusion (10 subjects) or partly adjustable appliance (14 subjects) titration not described

mild mod OSA (AHI >10 and <50), dental criteria adequate, age >18/OASA/severity, dental criteria/na/50.9/20m, 4/f/51.9/ns

Group MRA: pre mean = 22.9 (6) post mean = 8.0 (10.9) p = <.01. Group CPAP: pre mean = 22.2 (6) post mean = 3.1 (2.8) p = <.001. Group MRA: pre mean = 13.4 (4.6) post mean = 9.0 (5.1) p = <.001. Group CPAP: pre mean = 13.4 (4.6) post mean = 4.1 (4.1) p = <.001. Other: Arousals group MRA pre mean = 19.3 (9.6) post mean = 11.6 (5.6) p = <.01. Group CPAP: pre mean = 19.3 (9.6) post mean = 9.8 (6.6) p = <.01. 12/24 mild jaw discomfort early in the am, 1 stopped MRA due to side effects, 2 stopped CPAP due to SE

Adherence not stated. The MRA may be a suitable alternative to CPAP in patients with mild to moderate OSA. MAS were well tolerated and preferred by the majority of subjects.

14 Walker-Engstrom, et al//1//KF/1

RCT, comparison of an appliance at 2 settings, prospective, blinded evaluators, intention to treat analysis// Home, unattended (resp monitoring only)//MRA, partial occlusal coverage, custom //No! Protocol defined: yes, set at 75% to max protrusion or 50% maximum, end point criterion: advance

Severe OSA at > 20, age: 20-65, no drug abuse and no mental illness (pronounced malocclusion, severe cardiac, resp, neural disease, nasal obstruction//) Yes, 40 patients per grp for a power of 80% to detect a greater 25% difference in normalization rates

75% grp: pre mean = 50.4 ± 4.7, post mean = 15.6 ± 6.2, response = 69%, p = <.001. 50% grp: 47.0 ± 5.1, post mean = 17.4 ± 5.7, response = 63%, p = <.001. NS//75% grp: pre mean = 11.5 ± 3.1, post mean = 7.5 ± 2.6, response = 35%, p = <.001. 50% grp: pre mean = 11.7 ± 3.1, post mean = 8.6 ± 2.8, response = 26%, p = <.001. NS//50% grp: pre mean = 19.1 ± 7.0, response = 34%, p = <.001. ODI-50% grp: pre mean = 18.0 ± 6.0, response = 59.6%, p = <.001. // Snoring Index= 75% grp, 75% MRA grp- 77% success, 25% failed; 50% MRA grp-62% success, 38% failed// Index= 75% grp, 77% success, 25% failed; 50% MRA grp-62% success, 38% failed//Tx success AI < 5 and AHI < 10. 75% group- 52% success, 48% failed; 50% grp-31%; success, 69% failed; satisfied with Rx=90%

Patient selection: yes, confounding factors: no, patients were randomized to the two different groups, cross-over bias: no, errors in ascertainment: no, loss to fru: minimal - intention to treat, sample size calculation, severe OSA patients, detailed fru

Well-done adequately powered study that shows more advancement means more success with OSA MRA tx
measured: 50% group 5.0 mm (4.8 to 5.3) 75% group 7.2 mm (6.7-7.6) anterior opening measured: 2mm

with the more advanced appliance and alpha of 0.05/ 0.04 in 75% grp, 54.3 in 50% grp/ All male/ 30.2 ± 1.2 in the 75% MA group (no difference between grps) 30.5 ± 1.4 in the 50% MA group/50% reduction in airflow with a 4% desat

pre mean =0.86 ± 0.1, post mean = 0.57 ± 0.1, 34 %, p-value=0.001; 50% grp- pre mean = 0.83±0.1, post mean = 0.66 ± 0.1, response= 20.5 %, p-value= < 0.001/TMJ discomfort, 75% grp - minor-temp in 12.5%, none in 50% grp; Occlusal change, 75% group - minor-temp in 15%, 50% grp - minor-temp in 5% success, 10% failed; success defined as a decrease of 50% in AI of AHI- 75% grp- AI 68% failed, 12% success, 75% grp- AI B3% success, 17% failed; 50% grp- AI 78% success, 22 % failed; AHI 76% success, 24% failed// Lower BMI lower

5.0 mm (4.8 to 5.3) n: can be advanced

(6.7-7.6) anterior openning measured: 5mm interincisal

Wilhelmsson

RCT, prospective, comparison to baseline & alternative Rx (UPPP)// Home (respiratory monitoring only, unattended):// MRA, full occlusal coverage, custom// No/ Protocol defined: set 50% max protrusion (4-6mm), anterior opening measured: 5mm interincisal

Patient selection/NS, confounding factors: NS, crossover bias: NS, errors in ascertainment: NS, loss to f/u: significant in MRA grp, not in UPPP- Population: probably generalizable, intensity: mild to moderate OSA

Wilhelmsson, Walker-Engstrom ref both Teg and Wil) data from Tegelberg #84 regarding adherence & SE in MRA grp, data from Walker-Engstrom paper 88 for quality of life, data from Ringqvist (XO2) for long term side effects

Large prospective random study showing that OA is more effective than UPPP. Fours year use of OA with limited mandibular protrusion (50% max) and partial dental coverage (molars) produces no significant dental or skeletal change. Good long-term outcomes in OA group.
Engstrom (#89) after 4 years - TMJ: minor-temporary=1 patient, occlusal changes: minor-temporary=4 patients, severe-permanent=1 pt; Retention problems, broken plastic, broken clasps: minor-temporary, from Ringqvist (X02) Cephalometry: in comparison to UPPP group (no OA therapy) no change in skeletal or dental parameters except for minor elongation of incisors.

not factor in MRA grp, higher BMI more fall in AI in UPPP, PUAO: MRA grp-dominant obst in oropharynx (type I) in 24 pts, hypopharynx in 2, combo in 15, type 1: MRA success 96%, UPPP 77%, type II & III- MRA success 92%, UPPP success 59%, success not diff for diff obstruct types regardless of Rx grp/Walker-Engstrom (#89) after 4 years 72% of OA group successful Rx, UPPP group 35% success.
Barnes, et al. 1,5/WSN/1

1. Study Design/Location (type)/Oral Appliance/Adjust-titratable/Titration
- RCT, comparison to placebo grp, comparison to alternative treatment grp, crossover with CPAP, randomized treatment order, selected subjects, prospective/ Sleep lab (full PSG, attended)/ MRD, full, custom, Adjustable/ Protocol defined: maximal comfortable protrusion, end-point criterion: maximal advance tolerated, advance measured: 10.3 (0.3)

2. Selection Criteria (Exclude)/Sample Size Rationale/Age/Gender/BMI/Hypopnea
- OSA/severity, dental criteria (NS)/NS/47.0 (0.9)/80% MAI 31.1 (0.5)/Referenced

3. Outcomes AHI // O2 Sat // ESS // Other/AE
- Baseline grp: pre mean= 21.3 (1.3); CPAP grp: post mean= 4.8 (0.5), p=.001, vs MAD; MAD grp: post mean= 4.8 (0.5), p=.001. Placebo grp: post mean= 20.3 (1.1), p=NS/ Baseline grp: 86.7 (0.6); CPAP grp: post mean= 91.9 (3.0), p=.001, vs MAD; MAS grp: post mean= 87.6 (0.4), p=.001. Placebo grp: post mean= 95.4 (0.6), p=NS/ Baseline grp: pre mean= 10.7 (0.4); CPAP grp: post mean= 9.2 (0.4), p=.001. MAD grp: post mean= 9.2 (0.4), p=.001. Placebo grp: post mean= 10.2 (0.4), p=NS/ FOSQ- Baseline grp: pre mean= 3.1 (0.1); CPAP grp: post mean=3.3 (0.1), p=.001, MAD grp: post mean= 3.3 (0.1), p=.001. Placebo grp: post mean= 3.3 (0.1), p=.001. SF36- Baseline grp: pre mean= 69.4; CPAP grp: post mean= 74.1 (1.2), p=.001; MAD grp: post mean= 73.7 (1.2), p=.001. MWT- Baseline grp: pre mean=30.7 (0.9); CPAP grp: post mean= 30.0 (0.9), p=NS; MAD grp: post mean= 28.9 (0.9), p=NS; Placebo grp: 28.9 (0.9), p=NS/ NS

4. Categorical Tx-Snoring/Other/Predictors
- NS/ MAD, Success- AHI<10 grp: 49.1% success; AHI<15, no sx grp: 55.2% success/ NS

5. Internal Bias // External Bias
- No adverse effects on TMJs or stomatognathic system were shown after 2 years use, but minor occlusal changes were found

6. Reviewer Comments
- No adverse effects on TMJs or stomatognathic system were shown after 2 years use, but minor occlusal changes were found

Study Conclusion
- A MAD is an effective treatment in CPAP failed OSA patients, but the TRD and SPL are not.
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<tbody>
<tr>
<td>1</td>
<td>Author</td>
<td>Citation</td>
<td>Questions/Reviewers</td>
<td>Evidence Level</td>
<td>Study Design</td>
<td>Location (type)</td>
<td>Oral Appliance</td>
<td>Adjunct-irrigatable/Irrigation</td>
<td>Selection Criteria Include (Exclude)</td>
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<td>2</td>
<td>Clark</td>
<td>16</td>
<td>1,4,KF-RC/3</td>
<td>Non-randomized controlled trial, crossover with CPAP, prospective, evaluators blinded/ lab (PSG, attended)</td>
<td>IMDR, herbst app, full occlus, custom/adjustable/NS</td>
<td>OSA-severity-AHI &gt;15, nasal patency, dental crit-good prot range &gt; 7mm, age 21-75 yrs, other-good nasal airway, good health</td>
<td>Substantial success in most cases less effective than CPAP overall, less effective in more severe cases. AMP preferred as long-term treatment option, this preferred biased in that it was provided free</td>
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<td>Clark</td>
<td>18</td>
<td>3,4,KF-RC/5</td>
<td>Consecutive subjects, retrospective, unblinded case series/lab (PSG, attended)</td>
<td>IMDR, Klearway, full custom/irrigatable/initial setting was 60% maximum protrusion, PSG done, if symptoms persisted appliance advanced 0.5 mm per week. End-point criterion: Yes, 10.3 ± 1.6 mm, anterior opening measured 2 mm</td>
<td>Mid-moderate OSA, other-using amp for at least 1 yr (NS)</td>
<td>AMP success =20N, failed=1N, 5% fail, grp amp success=20N, failed=1N, 5% fail, intolerant CPAP &amp; amp, other-at 3-10weeks, grp CPAP success=17N, cont. use/NO PREDICTORS</td>
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<td>De almeida</td>
<td>New</td>
<td>4,KF/5</td>
<td>Case series, comparison to baseline/lab (full PSG, attended)</td>
<td>IMDR, Klearway, full custom/irrigatable/initial setting was 60% maximum protrusion, PSG done, if symptoms persisted appliance advanced 0.5 mm per week. End-point criterion: Yes, 10.3 ± 1.6 mm, anterior opening measured 2 mm</td>
<td>Include-OAS/sex/age-AHI 5 to 30, dental criteria &gt; 10 teeth each jaw, age &gt; 25, BMI &lt; 33</td>
<td>Ampl success=17N, cont. use/NO PREDICTORS</td>
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<td>Denbar</td>
<td>108</td>
<td>7,RR accept, WSN reject/case report</td>
<td>Case series, cephalometry compared to control group at baseline/lab (PSG, attended)</td>
<td>IMDR, TAP/auto-irrigation, CPAP, OC, custom/yes/protocol defined</td>
<td>Jaw position determined by serial x-ray studies</td>
<td>Case study: pre AHI 85.0, post AHI TAP 40 (56% decrease), AHI with TAP + CPAP 7.0 (92% decrease)</td>
<td>Case study: pre AHI 85.0, post AHI TAP 40 (56% decrease), AHI with TAP + CPAP 7.0 (92% decrease)</td>
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</table>
| 6 | Endo | X03 | 9,7,WSN/3 | Case series, cephalometry compared to control group at baseline/lab (PSG, attended) | IMDR, TAP/auto-irrigation, CPAP, OC, custom/yes/protocol defined | Jaw position determined by serial x-ray studies | Cephalometry, baseline: Compared to controls, patients demonstrated micrognathia, low latency enlarged tongue, low lying hyoid bone. Cephalometry, treated: Compared to baseline, patients with a better reduction in AHI had a 'balance relationship' between maxilla, mandible. | Internal validity: Limited description of patients and controls prevents drawing conclusions. Japanese OSA patients appear to differ from controls by craniofacial features (micrognathia), and treatment success is correlated with cephalometric findings
1. Single\n\n**Citation:** 06.1,3,5,6/KF-RC/1\n**Study Design:** Randomized controlled crossover, comparison to CPAP; consecutive subjects, prospective. PSG scored blinded/baseline PSG in lab, ft/home. Resp mont, unattended\n**MRS 1 custom, full; MRS 2 custom, partial/adjustable/crossover after 2 months on each RX, prot def: set at 80% max mand protrusion, ant open meaus 2-4 mm\n**Selection Criteria:** MRS-age 18-70, OSA-severity: AHI >4, effect size: 57 CPAP vs MRS, <0.001; Grp MRS mean ESS 14 ± 4, post mean 13 ± 3, grp CPAP post mean 14 ± 4, p < 0.05. Grp MRS success (AHI <10) 31 (66%), CPAP success (AHI <10) 22 (47%). Grp CPAP success predictors of Rx preference: higher BMI, greater daytime impairments tended to prefer CPAP vs MRS\n**Outcomes:** AHI, O2 Sat, ESS.\n**Reviewer:** Engleman 96, Eveloff 24, Ferguson 25, KF-RC\n**Study Conclusion:** Overall, MRS appears to be a reasonable alternative for some patients with mild OSA.

2. Eski\n\n**Citation:** 23, 1, 2, 6/UT/1\n**Study Design:** Case series, comparison to baseline, prospective, blind study evaluation/lab (PSG, attended)/IMRD-herbst, full occ cov, custom/not titrated\n**Selection Criteria:** Grp AMP age mean 44.2, post mean 31.5, p < 0.05. Grp AMP success 6, fail 2. Grp AMP predictor: AHI MAD advance in responders.\n**Outcomes:** AHI, O2 Sat, ESS.\n**Reviewer:** Eski\n**Study Conclusion:** Overall, AMP appears to be a reasonable alternative for some patients with mild OSA.

3. Eveloff\n\n**Citation:** 24, 1,3,6/KF-RC/5\n**Study Design:** Case series, comparison to baseline, prospective, blind study evaluation/lab (PSG, attended)/IMRD-herbst, full occ cov, custom/not titrated\n**Selection Criteria:** Grp AMP age mean 43.4, post mean 34.7, p < 0.05. Grp AMP success 28, fail 24. Grp AMP predictor: AHI decrease in responders.\n**Outcomes:** AHI, O2 Sat, ESS.\n**Reviewer:** Eveloff\n**Study Conclusion:** Overall, AMP appears to be a reasonable alternative for some patients with mild OSA.

4. Ferguson\n\n**Citation:** 25.1,3,4,5/WSN/1\n**Study Design:** Randomized cross-over with other appliance with CPAP/lab, home (PSG, attended)/IMRD, full occ cov,custom/trimtable/NS\n**Selection Criteria:** Grp AMP age mean 56.5, post mean 45.4, p < 0.05. Grp AMP success 56, fail 10. Grp AMP predictor: AHI decrease in responders.\n**Outcomes:** AHI, O2 Sat, ESS.\n**Reviewer:** Ferguson\n**Study Conclusion:** Overall, AMP appears to be a reasonable alternative for some patients with mild OSA.
Fransson 103 1,2,6 /KF-NS/NS
Case series, comparison to baseline, consecutive/not stated (oximetry)/MRD full, custom, closed ant dimension (No/No/75% of max protrusion or at least 5mm, advance measured 6.1 ± 1.8 mm, ant opening measured 6.4±2.0 mm

Snoring or OSA, sufficient number of teeth, adults (max protrusion < 6 mm, severe canines, periodontal disease)/54.9 ± 8.0 (31-73)/13, 52 M/29.2 ± 3.6 (21-38)/NS

NIB/Mt SaO2; Grp OSA premean 79% (59-91 range), post mean, NA, Grp snorers, premean 92% (87-98 range), post mean NA -/NS/

Other oxygen desaturation index Grp OSA premean, 14 (5-61 range), post mean, NA; Grp snorers pre mean 1 (0-3 range) post mean, NA; Other, LUMI, Grp advance 1.5 * p < 0.05; Other, Pharynx area, Grp all pre mean 688.7 ± 248, post mean 727, response +58.3 8.7% incr, p < 0.001; Other, MPH, Grp all: premean 21.2 ± 4.6 mm, post mean 22.8 ± 1.6mm 7.5% incr, p < 0.001; Other, SBNB, Grp all -0.4 *p<0.01 not stated

NSIB/NSIB

Fransson 109 2/KF/FS
Consecutive case series, comparison to baseline, prospective/NI/NS/oximetry)/MRD full, custom, closed ant dimension (No/No/75% of max protrusion and at least 5mm from retruded position, advancement 8.4±1.1mm, anterior opening: 8.9mm±1.150

Snoring, OSA, enough teeth, protrusion range <6mm (severe canines or periodontal disease)/N=77, no sample size rationale/54/83M, 14/F/NS/NS/NS/NS

ns/ns/ns/others: ODI (1 hr); OSA: pre mean=14±1.6 post mean=n/a; Snorers: pre mean/ns post mean; other: Mean Oxygen Nadir: OSA pre mean=78±6.2 post mean; Snorers: pre mean/ns post mean

Other: MPH upright pre 21.4 ± 4.7 post 15.0 ± 5.3, 30% decrease/ns/ns

NSIB/NSIB

Fransson New 1,6/KF/FS
Case series, comparison to baseline, consecutive selected subjects, prospective/sleep lab (resp monitoring only, attended)/IMRA, full, custom/yes-one piece design/not described

OA or snoring, patients who failed other Rx were all included/dental criteria/protrusive range < 6mm, edentulous, poor teeth)/N=65, no ss rationale/OA 56 yrs (31-73) Snoring 52 (37-70)/I52, 13/F/OSA 30 (range 21 to 38) scoring 28 (23-35) NC: OSA 42.5 cm (range 37-5.1) snoring 39.9 (34-46)/NA

ns/(desat) OSA n=39, ODI pre mean=14±7.12, post mean=3± 4.2, 79% decrease, p-value<0.001 NS/NS/Oxygen desaturation index Grp OSA premean=78±8.1, post mean=89 ± 4.7, 14% increase, p-value< 0.001/NS/Snorbing time: Back: pre mean=81.1± 14.2, post mean=67.5± 19.7, 16.8% decrease, p-value<0.001. Side: pre mean= 85.9 ± 48.1, post mean= 48 ± 20, 72% decrease, response, p-value<0.001/NS

NSIB/NSIB

Fransson New 1/KF/FS
Case series, comparison to baseline, consecutive selected subjects, prospective/sleep lab (resp monitoring only, attended)/IMRA, partial, custom/No/NS/75% of max protrusion, range 5 mm, anterior openings measured/no, protrusive range measured=yes

snoring or OSA, OA=ODI >/ 5, adequate # teeth, (dental criteria/max protrusion) <5mm or periodontal disease, indications for bellevue or trach)/N=35, no ss rationale/52.9 ± 9 (36-70)/152, 3/F/OSA 30 (21 to 38), NC: 40.5±3.5 (33 to 50)/No

ns/Oxygen desaturation index: OSA 22, pre mean=15.4 ± 13.4, post mean ±3.3 ± 3.7, response=77%, p-value=0.001. Oxygen saturation level: OSA 22, pre mean= 81.9 ± 11, post mean= 85.7 ± 8.0, response=59%, p-value= NS/NS/means snoring time supine: 25, pre mean=75.2%, post mean=59.7%, response=21%, p-value=0.001/28% teeth not meeting in am, minor-temp

grp 29, success=24, failed=5, 83% success, 17% failed./Daytime tiredness: 24, success=16, failed=8, 67% success, 33% failed

controlling factors/ma, crossover bias/err, errors in ascertainment/pts probably used the tx can’t be sure/population-probably, intensity=milder end of the spectrum

Well-done large case series with two follow up points at 6 months and 24 months showing persistent benefit, limitation is that the oral appliance protocol was not described, side effects not mentioned

Fritsch 28 1,3 /KF-RC/FS
Randomized controlled trial (crossover), comparison to baseline and with 2 different appliances, prospective/ sleep lab (PSG, Attended)/Herbst and Monobloc 3 weeks each, Protrusion 75% of max, (4.3 to 10.1mm) opening 8.7-16.8mm/ADJUSTABLE//TITRATION?

CPAP failures or refusers AH15, Snoring with arousals>20/2/No/22/NS/NS/NI/26/8/ Hypo decrease no+ 25% for 10 secs in calibrated respitrace sum

16 patients preferred Monobloc, 5 preferred Herbst, 1 no preference. Pre AH1 29.7 ± 3.5 post with preferred 6.3± 14/NO OZ SATI/ESS/20: 12 (10-14) post- 8 (6-10) Snoring Index pre- 58.7±7.3 post- 23.7±4.6/NO OTHER/NO AE

7 subjects (32%) occultive changes/from cephs and models: Decrease in overbite and overjet, increase in the mean upper incisors to maxillary plane angle. MISSING EITHER OTHER OR PREDICTORS

NS, NS, NS/NI/Population likely generalizable, intensity mild to moderate OSA

Careful document of side effects on long term use. Up to 30 months. Occlusal changes more common than previously thought
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<th>Author</th>
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<th>Question//Evidence Level</th>
<th>Study Design//Location (type)//Oral Appliance//Adjust-titratable//Titration</th>
<th>Selection Criteria Include (Exclude)//Sample Size (Rationale)//Age/Gender//BMI//Hypopnea</th>
<th>Outcomes AHI // O2 Sat // ESS//Other//AE</th>
<th>Categorical Taxonomy//Other//Predictors</th>
<th>Internal Bias//External Bias</th>
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<th>Study Conclusion</th>
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<td>Gale</td>
<td>29</td>
<td>1.2/WSN/5</td>
<td>Case series with crossover/NS (NS)/MRD-yes, full occ cov, custom/not adj, 75% max anterior/NS</td>
<td>Dental criteria, age (dent crit)&lt;Yes/51.5 (11.9)/27 M, 5F/28.6 (4.5) // NS</td>
<td>Grip pre-mean 28.6 (19.3) // NS (other group pre-mean 80.22 (48.1) SD, resp 28.34 (59.06), p &lt; 0.01//NS</td>
<td>Patient sel-yes, confound fact-dental sel factors//pop-clinic, intensity-mod</td>
<td>MRD increases UA size especially in the high oropharynx in diameter and cross-section. Smaller lingual size, larger increase in oropharyngeal space predicts response</td>
<td>OA significantly increased minimum pharyngeal cross-sectional area suggesting it may be an effective therapy for OSA</td>
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<td>Gao</td>
<td>30</td>
<td>1.2,6/KF-RC/5</td>
<td>Case series, comparison to baseline, prospective, blinded/PSG scoring/sleep lab (PSG, attended)//MRD not named/NS/NS</td>
<td>OSA mild to severe (NS)//N=11 no sample size rationale//Age 49.5±7.2//9 M, 2 F/ BMI 27.2 ± abstract, 23.9 ± 2.3 in text/Hyp-decreased airflow, ongoing effort, 4% desat + arousal</td>
<td>AHI 44.9±25.2 to 9.6±6.3, 78% decr, no p given//Low SaO2 71.4±15.0 to 82.0±17.7, 15% incr, no p given//N=1/MR(I) oropharynx change 5555.9±4239.1 to 6662.9±2260.0, 24% incr, p&lt;0.001; other-whole airway, pre-mean 122666± 4129, post-mean 132926.37 ± 4576, 13.5% incr, p&lt;0.01//NS/NO AE</td>
<td>NS/NS/small tongue and large oropharynx predict better decrease in AHI</td>
<td>N=11 NS, NS, NS. Don’t know, not mentioned//population not well described, good range of severity</td>
<td>OA increases UA size especially in the high oropharynx</td>
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<td>Savitch</td>
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<td>1.2/WSN/5</td>
<td>NS/lab (PSG, attended)//MRD-funct magnetic syst, full occ cov, custom/yes/prot def: minor all made to improve efficacy per patient report, adv meas: approx 5.0mm (60%max), ant open meas: 11.4 mm</td>
<td>Snoring, dent crit, age (OSA-severity), dent crit, age//No/50.5 (2.6)//9M, 1F/17±2.2 (2.0) // 50% airflow + arousal</td>
<td>Grip pre-mean 25.0 (10.65), post-mean 15.0 (8.1), p&lt;0.01 // grip pre-mean 88.1 (4.95), post-mean 90.40 (3.13), pval .043 // grip pre-mean 6.65, post-mean 7.28, pval 0.013//other/oral cavity, grip AOD pre-mean 9.44 (3.32), post-mean 14.33 (5.63), p &lt; 0.01, grip MOD pre-mean 8.89 (3.41), post-mean 12.22 (4.60), p&lt;0.04, grip ADA pre-mean 27.24 (10.79), post-mean 40.22 (14.89), p &lt; 0.016</td>
<td>Patient sel-yes, confact-sele(TMJ, dent)//pop-selec camp, intensity-mod</td>
<td>NS/NS/NS</td>
<td>Anterior region of oral cavity increased in size, correlated strongly to decrease in RDI, no increase in oropharyngeal airway size noted</td>
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</tbody>
</table>
| Gotsopoulos | 100   | 1.4/KF-RC/1             | Randomized controlled trial, comparison to placebo grp, crossover with placebo app, prospective, consecutive, double blind/lab (PSG, attended)/IMAS, full occ cov, custom/If titrate/prot def: wore MAS for acclim period (9 ± 4 wks)-incremental advmnt till max comfort limit| OSA-sev: AHI > 10, dent crit activity to protrude mand by ≥3mm, age >20yrs, other-at least 2 symptoms include EDS, snoring, witnessed apneas, frag sleep (dent crit-insuffic teeth, bad gag reflex, periodontal dis or dental decay, other-central sleep apnea psychosis disease, narcotic or sedative or psychoactive drug use)//NS/44±11//195M, 14 F/29 ± 4.7//citation | MAS premean AHI 27.1±15.3, post 12 ± 2, 55.6% decr, p=NS, Grip placebo pre-mean AHI 27.1±15.3 post 25±2.7, 7.7% decr, p=NS, MAS vs. Control p<0.0001//Grip MAS pre-mean minSaO2 86±8, post 89±1.3, 3.5% incr, P<0.001, MAS placebo pre-mean 86±1, 0% change, P<0.001 MAS vs Control/Grip MAS pre-mean ESS 11±6, post 7±1, 36.3% decr, p<0.001, Grip placebo pre-mean 11±6, post 9±1, 18% decr, P<0.01, P<0.001 MAS vs placebo, (82% normal ESS in MAS vs 62% placebo, p<0.1)//Other-Arousal index, grp MAS premean 35±13.5, post 25±2.8, 28.6% decr, p<0.01, Grip placebo premean 35±13.5, post 33±2, 5.7% decr, Other-Sleepiness-MSLT (min), Grip MAS post mean 10.3 ± 5, Grip placebo post mean 9.1 ± 5, P<0.01 for MAS vs placebo, (48% normal MSLT MAS, large 34% normal MSLT placebo), Other-Snoring Freq, (snorers per hr), Grip MAS post 207±20, Grip placebo post 366 ± 21, snoring freq much less w MAS (P<0.0001) snoring intensity less w MAS/NS/Pain: min-temp, jaw discomfort more common w MAS, other: min-temp, more tooth discomfort w MAS, more excess saliva w MAS | Other-complete resp (AHJ<5 per hr) Grip MAS 26 succ (36%)//Grip placebo 0 succ (0%), Partial resp (AHI down by 50% but<5) Grip MAS 20 PR (27%)//Grip Placebo O PR, Trtmnt failure (AHI not down by 50% or <5) Grip MAS 27 failure (37%)//Grip Placebo 73 failure (100%)/NS | NS, NS, crossover bias: no trtmnt by period interaction or period effects from MSLT, ESS, or PSG variables, errors in ascertainment: good careful monitoring, loss to follow: not a prob/Pop: yes, likely generalizable, intensity: good range of severity | More patients reported improved frequency & intensity of snoring with MAS, more patients reported improved sleep quality with MAS, more patients reported satisfaction with MAS, More good snoring measurement objectively obtained, well done, thorough follow-up, no effect of placebo size | Large randomized placebo controlled study showed that MAS improve snoring, AHI and both subjective and objective sleepiness.
<table>
<thead>
<tr>
<th>Author</th>
<th>Citation</th>
<th>Question/Reviewer//Evidence Level</th>
<th>Study Design//Location (type)//Oral Appliance//Adjust-titratable//Titration</th>
<th>Selection Criteria Include</th>
<th>Outcomes AHI // O2 Sat //ESS//Other//AE</th>
<th>Categorical Tx-Snooring //Other//Predictors</th>
<th>Internal Bias // External Bias</th>
<th>Reviewer/Comments</th>
<th>Study Conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hans</td>
<td>2,4//KF/2</td>
<td>RCT, comparison to alternative appliance, crossover with other appliance (device B to Device A), prospective//Home (unattended, respiratory monitoring only)//12 patients SnoreGuard, 12 patients modified SG without advance, partial, prefabricated//No//Protocol defined: SnoreGuard (device A) set with incisors edge to edge, – 6 to 8 mm forward protrusion, 6 to 8 mm ant opening, Device B: no advancement and 1 mm ant opening, Advance measured: yes, Anterior opening measured: yes</td>
<td>Snoring, no systemic disease (OSA/severity:AHI &gt;30/hour (unless referred), dental criteria: edentulous subjects, age: minors, chronic disease, sed-hypn meds, pregnant women, prisoners, minors, mental disability, previous surgery for OSA, other sleep disorders, severe EDSS//NS//51.9 ± 12.3 (range 25 to 69 years))/20M, 4F/NS</td>
<td>SnoreGuard (10 subjects) grp: pre mean=35.6 ± 28.4, post mean=21.1 ± 21.4, p&lt;0.05; Device B (8 subjects) grp: pre mean=30.5 ± 43.7, post mean=46.8 ± 46.9, p=NS; All SnoreGuard (17 subjects) grp: 42.4 ± 37.5, post mean=29.7 ± 21.4, p&lt;0.05/NS//SnoreGuard (10 subjects) grp: pre mean=12.0 ± 3.9, post mean=8.2 ± 4.0, p&lt;0.05; Device B (8 subjects) grp: pre mean=13.0 ± 4.5, post mean=12.5 ± 5.7, p=NS; All SnoreGuard (17 patients) grp: pre mean=12.9 ± 4.4, post mean=9.6 ± 4, p=0.005/NS/NS</td>
<td>Patient selection: yes, by sleep study – but patients not well described in terms of symptoms, confounding factors: pts were similar in both groups. Said they were randomized but not how it was done, crossover bias (order effect): Nearly all patients using Device B crossed-over to the SnoreGuard, errors in ascertainment: not measured – but only a two week treatment period, os to flu: 33% lost in Device B, 17% lost in SnoreGuard group (Device A)! Population generalized: probably, intensity:good range of severity included</td>
<td>Not a bad study, small in numbers, but patients randomized to the groups, one appliance unlikely to be effective (Device B) due to absence of advancement of mandible and in that group most patients got worse, the SnoreGuard (Device A) was fairly effective even in severe patients.</td>
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<tr>
<td>Higurashi</td>
<td>X06</td>
<td>1//RR//5, no occlusal coverage, custom//NS/NS</td>
<td>OSA severity//NS/mean 59.4//Male 6, Female 2/Mean 25.3/NS</td>
<td>NS/All pre- 69 post-83.9/NS//ODI - all: pre- 40.5 post-10.7. 90%+SpO2 (%) all pre-19.78 post- 2.95/NS</td>
<td>NS/NS/NS</td>
<td>NS/NS</td>
<td>TRD positively effected cases of OSA by lowering ODI and time below 90% O2 desaturation, and by raising lowest O2 desaturations. Accept-although small N, one of only studies with TRD</td>
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<tr>
<td>Ishida</td>
<td>34</td>
<td>1,2,6//KF-RC//5</td>
<td>Case series, comparison to baseline, prospective//sleep lab (PSG)/PMA - not described//NS/NS</td>
<td>OSA mild to severe//N=19, No sample size rationale//Age 52.8/ 19 M/BMI 28/NS</td>
<td>AHl pre 37.8±28.3 to post 12.9±14.6, 66% decre, p=0.001//Low SaO2 pre 78.3±19±3 to post 85.3±8.2, 9% incr, p=0.01/NS</td>
<td>NS/All n success: 13 (68.4%), n failed: 6 (31.5%), 68.4% success, 31.5% fail, cat effect: other-staged intraesophageal pressure sigmoid dummy PMA comp to pre PMA (&lt;p&lt;0.05); sleep architect- arousals #, % stage 1 sig dec (&lt;p&lt;0.01) in cases w AH1 &gt;30 bef PMA, sleep arch improved only in severe cases//MRI with and without PMA during day nap</td>
<td>Patient sel- not sure, clin feat not desc, sel crit not defined, conf fact: pre, post comp-short time b/w measurements, grps prob unchanged, no comp grp, errors in ascertain- not obj meas/pomp- not comp sure, prob, intens- not desc but pre AH1 37.8 ± 28.3-mean is severe range</td>
<td>Not great paper but studied more severe patients, patients thinner and Japanese, assessed predictors of outcome, useful and did MRI pre- and post-treatment, main problem- paper too short, much detail missing</td>
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<tr>
<td>Johnston</td>
<td>106</td>
<td>1,3,4//WSN-RR//2</td>
<td>Randomized controlled trial, comparison to placebo group//home, unattended/resp monitoring//RRD/No/NS</td>
<td>snooring, OSA/severity, dental criteria(ns)/yes//55.1/16m, 47/31.6/90% reduction in air flow</td>
<td>Group MAA: pre mean=31.9(21.2) all pts post mean=22.9(22.2) p&lt;0.01 OA vs placebo. Group Placebo: post mean=37.7(24.9) //NS/MAA; pre mean=13.9(6.4) all pts post mean=11.6(6.7) p&lt; NS OA vs placebo. Placebo: post mean=12.6(6.3)/other//OD-MAA: pre mean=30.7(18.8) all pts post mean=21.1(19.8) p=0.02 OA vs placebo. Placebo: post mean=31.2(18.2)</td>
<td>NS/NS//CATEGORY MISSING</td>
<td>treatment position determined a priori, not adjustment for effect/NS</td>
<td>Not clinical variables predict response. MRI shows glosso- pharyngeal obstruction is corrected by PMA</td>
<td></td>
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</tbody>
</table>

- **Study Design/Location (type)//Oral Appliance//Adjust-titratable//Titration**: The study design, location type, oral appliance, and adjustment titratability are described. For example, a randomized controlled trial (RCT) with an oral appliance comparison to another appliance, prospective study with home monitoring, and no adjustment titratability.

- **Selection Criteria Include**: The selection criteria include considerations such as age, gender, BMI, and hypopnea. For example, with inclusion criteria of age, gender, BMI, and hypopnea.

- **Outcomes**: The outcomes measured include AHI (Apnea-Hypopnea Index), O2 Sat (Oxygen Saturation), ESS (Epworth Sleepiness Scale), and AE (Adverse Events).

- **Categorical Tx-Snooring //Other//Predictors**: The categorical treatment includes information about snoring, other predictors, and other variables.

- **Internal Bias // External Bias**: This section describes the internal and external biases associated with the study.

- **Reviewer/Comments**: The reviewer comments on the study, including its strengths, weaknesses, and general conclusions.
Case series comparison to baseline, prospective, retrospective/NS (aximmetry, unattended)/MRD, full, custom/fixed but 3 versions of progressive advancements/2 mm per week, advancement measured 2.4, 6, 8 mm; anterior openness measured 5-8 mm

**Selection Criteria Include**
- Exclude
- Sample Size
- Rationale
- Age
- Gender
- BMI
- Hypopnea

**Outcomes**
- AHI // O2 Sat // ESS // Other/AE

**Categorical Tx**
- Snoring
- Other/Other

**Internal Bias**
- External

**Reviewer**
- Comments

**Study Conclusion**
- Help define mechanism
- Step advancement of mand pos resulted in dose-depend reduction of closing press of passive pharynx. Improvement of both oxygenation and pharyngeal collapse significantly depends on the mand. Position

**Other/AE**
- Other

**Bias**
- Internal

**Evidence Level**
- Appliance
- Adjust-titratable

**Study Design**
- Location (type)
- Oral

**Selection**
- Titration

**1**

**Kato**

**New**

**42**

**Liu**

**42**

**Liu**

**33**

**30**

**Kingshott**

**New**

**42**

**Grp advance 0 mm, mean ± SD = 17.3 ± 3.0, p < 0.05; Grp 2 mm, mean ± SD = 17.7 ± 3.1, p < 0.05; Grp 4 mm, mean ± SD = 16.2 ± 3.3, p < 0.05; Grp 6 mm, mean ± SD = 13.5 ± 3.3, p < 0.05; compared to 0 mm.

**AHI**

- Pre mean = 26 ± 17, post mean = 15 ± 13, response = 42.3% decrease, p-value = 0.004.
- Pre mean = 34 ± 16, post mean = 22 ± 14, 35% decrease, p-value = 0.004.
- Pre mean = 30 ± 10, post mean = 15 ± 8, 50% decrease, p-value = 0.004.

**SaO2**

- Pre mean = 95% CI = 86.2 (75.4-91.5), post mean = 95% CI = 93.3 (88.5-95.1), p < 0.05.
- Pre mean = 95% CI = 85.6 (78.1-91.9), post mean = 95% CI = 91.1 (85.6-95.6), p < 0.05.

**Snoring**

- Pre mean = 41 ± 52, post mean = 8 ± 16, 80% decrease, p-value = <0.046.
<table>
<thead>
<tr>
<th></th>
<th>Author</th>
<th>Citation</th>
<th>Question/Reviewer</th>
<th>Evidence Level</th>
<th>Oral Device</th>
<th>Initial Selection Criteria</th>
<th>Outcomes</th>
<th>Categorical Tx</th>
<th>Internal Bias</th>
<th>Study Conclusion</th>
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</thead>
<tbody>
<tr>
<td>34</td>
<td>Liu</td>
<td>1,2,4/ KR-RC/5</td>
<td>Case series, comparison to baseline, prospective lab (PSG attended)</td>
<td>MRD full occl not adjustable</td>
<td>Oral appliance</td>
<td>OSA &gt;10 AHI (exclude AHI&lt;5, AHI&lt;10, period, TMJ)</td>
<td>AHI 40.3±21.7 to post 11.7±11.8, 71% decr, p&lt;0.01; Low Sat pre 73.4% ± 8 vs 76.9% ± 8.3% incr, p&lt;0.01; Other-titratable</td>
<td>Shiong 8/22 (81.8%) success/treatment succ: AHI &lt; 10, Grp all 13/22 (59.1%), 9/22 (40.9%) failure, Grp mild-mod 7/8 (87.5%) success, 1/8 fails (12.5%), Grp severe 6/14 (42.9%) success, 8/14 (57.1%) failure</td>
<td>NS, NS, NS, NS, NS</td>
<td>Study done case series. No sample size calculation and statistics poorly reported, but confirms MAD better results with mild to mod RDI than with severe OSA</td>
</tr>
<tr>
<td>35</td>
<td>Liu</td>
<td>New NS/NF/5</td>
<td>Case series, comparison to baseline, prospective lab (PSG attended)</td>
<td>Full occl, titratable</td>
<td>Oral appliance</td>
<td>OSA/severity-mild to severe (AHI &gt; 15), dental criteria-10 teeth each jaw, normal mandibular movement, in metro Vancouver (dental criteria-TMJ problems)</td>
<td>All pre- 33.4-4 12.5 post-11.2 7.7 p value &lt; 0.001; Good Response (AHI ≤15) n = 11 pre-29.2 post-7.0 4.5 response-78%; p value&lt; 0.001; Poor Response (AHI &gt;15) n = 5 pre-30.9 post-20.4 3.9 response-34%; p value&lt; 0.001/AH: pre- 77.0 9.6 post- 82.6 6.7 response- 7%  p value 0.05/NS/NS/NS</td>
<td>NS/NS/NS</td>
<td>NS/NS/NS</td>
<td>Information on predictors of outcome that is important</td>
</tr>
<tr>
<td>36</td>
<td>Lorino</td>
<td>2/ WSN/5</td>
<td>Case series/NS (NS)/other-wax bite, 5-6 mm adv/NS/NS</td>
<td>None</td>
<td>Oral appliance</td>
<td>NS (NS)</td>
<td>NS/NS/NS/NS/NS</td>
<td>NS/NS/NS</td>
<td>NS/NS/NS</td>
<td>NS/NS/NS</td>
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<tr>
<td>37</td>
<td>Lowe</td>
<td>1,2,3,4/ WSN/5</td>
<td>Case series, comparison to baseline, prospective lab (PSG attended)</td>
<td>Full occl, titratable</td>
<td>Oral appliance</td>
<td>Dent crit (dent crit)](get real)[44/36M, 2F/30.3/NS</td>
<td>Pre- mean 32.6±2.1 (SEM), post- mean 12.1 (1.7 SEM), p &lt; 0.0001/NS // NS // other: outcome: airway video (n=9) shows inc at all levels, sig only @ velopharynx</td>
<td>NS/other success = no sympt + RDI &lt; 15 def., grp all: 71% succ, RDI &gt; 30: 80% succ, RDI 30+: 39% succ</td>
<td>NO PREDICTORS</td>
<td>patient sel: yes, conf fact: sel factors/ NS</td>
</tr>
<tr>
<td>38</td>
<td>Marklund</td>
<td>4/RR/3</td>
<td>Non-randomized controlled trial/NS/NS</td>
<td>MRD-MAD hard acrylic, MAD soft elastomer, full &amp; part ortho</td>
<td>Oral appliance</td>
<td>Other-treat with OA for OAT (NS/NS)</td>
<td>NS/NS/NS/NS/NS</td>
<td>Subjective 37/68 with no change, 28/69 altered occlusion disappears over time, 38/69 permanent change in occlusion</td>
<td>NS/NS/NS</td>
<td>After mean 2.5 yrs OA use, changes occ studied, diff in app design hand &amp; soft, obsld as related to occ changes: treatment induced mean changes overjet, overbite, arch width both app types, changes to be unrelated deg protri, 3pts out 60 resp to quest were aware of perm bite changes, follow up import pts freq unaware of occ changes, smallf changes occ seen in pts use soft OA</td>
</tr>
<tr>
<td>Author</td>
<td>Citation</td>
<td>Question/Reviewer</td>
<td>Evidence Level</td>
<td>Study Design/Location (type)/Oral Appliance/Adjust-tratble/Irritation</td>
<td>Selection Criteria include</td>
<td>Outcomes AHI // Oz Sat //ESS //</td>
<td>Categorical Tex-Snooring //Other/Predictors</td>
<td>Internal Bias // External Bias</td>
<td>Reviewer</td>
<td>Comments</td>
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<tr>
<td>Marklund</td>
<td>50</td>
<td>1.6/KF- RC/7</td>
<td>Case series, comparison to baseline, prospective, sleep lab (PSG attended) // MRD full occl cov, custom, fixed adjusted to maximize effectiveness? Protrusion 58% of max, 6mm median</td>
<td>OSA severity, CPAP decliners, (exclude dent crit, BMI=60, CSA/) // N=47 // no sample size rational // Age 58 (37-72) // 40 M, 4 F / BM 22 (22-37) // Hypop decrease airflow ≥50% plus ≥23% desat</td>
<td>Marklund 21 (24) 11.0 (8.5-15.9) to 6.3 (5.3-7.3) p&lt;0.01; Mod; AHI (15 pts) 27 (20-38) to 7.2 (1.3-19) p&lt;0.01; Severe (5pts) 53 (44-68) 14 (1.5-32) p&lt;0.01 (median values) NS NS NS NS; Grp mild pre med 6.5 (2.7-14.4) post med 3.9 (0.6-12.4) -40% resp; p =0.08; Grp mod pre med 24 (9.0-51) post med 9.9 (7.1-5.7) -71% resp; p =0.08; Grp sev pre med 53 (19-72) post 14 (2.6-33) -74% resp. p 0.04/Apical shkt - REM; Grp mod pr med 15 (10-22) post 21 (7.3-34) +40% resp p =0.05; Grp mod pr med 16% (8.1-26) post 21% (19-27) +31% resp p =0.02; Grp sev pr med 14% (6.18) post 20% (5.9-28) +3% resp; p 0.01 (N=44); Grp mod pr med 13 (5.1-26) post 8.5 (2.5-16.5) +35% resp p=0.01; Grp mod pr med 23 (10 -37) post 10 (5.3-28) +36% resp; p =0.02; Grp sev pr med 30 (20-67) post med 16 (6-28) +53% resp; p =0.01 NS; Grp mild pr med 7.3% (3.0-22) post 8.6% (0.18) +13.6% resp Grp mod 8% (0.17) post 7.2% (2.2-23) +19.4% resp p =0.004; Grp sev pr med 0.2% (0.3-3) post 8.8% (9.6-17) +4300% resp p =0.01/NS</td>
<td>Snoring mild Grp: 20 Success 1 Failure; Grp Mod 125 3F Grp Severe 55 3F EDS 34/42 (81%) success 8/42 (19%) failure; Success Grp mild 20/21 (95.2%) success; Grp mod: 12/15 (80%) success, Grp sev: 5/8 (62.5%) success/ Combined Success Score AHI &lt;10 &amp; satls snoing Grp: mild7/21 (81%) success, Grp mod 9/15 (60%) success, Grp sev: 2/5 (20%) success, GROUP ALL 29/44 (64%) success. 16 pts unsatis result- 9 good snor but AHI not reduc; 2 AHI red but still snor, 5pts both snor &amp; high AHI/Poor result with less proctor ablity - needed at least 5 mm advancement to work. Better response with lower AHI.</td>
<td>Success with MRD is associated with a normal mandibular plane angle and a small lower anterior facial height</td>
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Marklund | 51 | 1.2/WSN/5 | NS/sleep lab (PSG, attended) // IMRD-yes, full occ cov, custom/adjustable/prot def: adj AHI > 10, anterior open meas: ≥5 mm | OSA surv AHI<20, other-not on cppap (NS) // NS// 57yrs/ all M/ median 28 kg per m2/ dec airflow <50% | Grp total: pre-mean 23 (med) post-mean 7.8 post-p=0.01, Grp supine: pre-mean 39 post-mean 11 p=0.01, Grp non-sup: pre-mean 15 post-mean 2.6 p <0.01; NS/NS/NS/NS | NS// other/treatment succ AHI <10, Grp sup AHI <15: N succ= 20, N fail =10, Grp non-sup, AHI <10: N succ = 26, N fail= 4 NO PREDICTORS | pt sel=yes, conf fact: sel for loss to follow: 0- pop yes, intens: full range/ Successful apnea reduction using MRD is associated with a normal mandibular plane angle and a small lower anterior facial height |

Marklund | 52 | 1.2,6/KF-RC/7 | Case series, comparison to baseline, consecutive, prospective/sleep lab (PSG, attended) // custom MRD/adjustable/Set 4-6 mm advance, open 5 mm, appliance adjusted if snooring persisted or if patient had end point - at flu- protrusion 10 mm (8-14) | OSA surv (AHI < 15 per hr or 30 minutes of sleep in lat or sup position) // N=20/median age sup to depend grp 59 (37-60); non-sup grp median 54 (37-60) // N=22, F=3/NS/NS/NS/dec >50% airflow in desat ≥3% | Grp N=12 supine dependent AHI - pred median 15 (6-5-27); post 3.4 (10-14) p<0.01; Sup AHI, post 14 (0.8-21) p=NS; Grp N=14 Non-SupDepAHI premed, 22 (11-33-32) p<0.01; Supine AHI, premed 44 (1.8-73) post 21 (6.15) p<0.02; Lateral AHI, premed 21 (12-70) post 4.5 (3.1-39) p<0.01/NS/NS/NS Other: arousal index; SupDep premedian 17 (7.4 to 26 post 8.2 (4.1 to 28) p<0.01; Non-SupDep premedian 24 (5.2 to 67) post 9 (13-27) <0.01/NS | NS //grp supine dependent AHI success 10/12; N= 21/29, 83% success, 10/12 supnosup success 2/14, N fail 12/14, 14% success; All N success 12/26, 14/26, 54% success NO PREDICTORS |成功与MRD相关的患者 | Patients with Supine dependent OSA (higher AHI supine) have a better result with an MRD |

Marklund | 53 | 1.3,4/WSN/5 | NS/lab (PSG, attended) // MRD- MAD, full occ cov, custom/no but re-constructed pr for adj/prot def: after 2 mo habit per, adj made due to se, insuff titrmt, end pt crit: lack se, effect sub reports, adv meas: 4:4mm, ant open meas: ≥ 5mm | OSA pts, snooring, OSA severity, can't tolerate CPAP (NS) // No // 50/12 | Grp 7 year, N=18 pre-mean 25 (16), post-mean 8.8 (7.6) p<0.01; Grp 5.2 yr, N=19, pre-mean 22 (17), post-mean 4.9 (5.1), p<0.01 // Grp 7 yr, N=18, pre-mean 80 (3.8), post-mean 87 (5.5) p<0.05; Grp 5.2 yr N=19, pre-mean 92 (3.1), post-mean 89 (5.4), p<0.05 // NS // OD/4 (Oxygen desat index %), Grp 7 yr, N=17, pre-mean 12.6 (7), post-mean 1.1 (0.6), gr p5.2 yr N=19, pre-mean 15 (14), post-mean 4.4 (3.3), p<0.05 // SE minor-temp; occlusive changes 219; severe permanent - occlusive changes 0/19 | Grp 5.2 yr, N=19, N success= 14, N fail = 5 // Sleepiness, Grp 5.2 yr, N=19, N success = 13, N fail = 6 CATEGORY MISSING | patients have apoprop disease, confounding factor selective follow-up at 7 yr, no loss to follow up - 14 patients received other therapy // pop generaliz - mild to mod OSA pop | 19 of 35 patients suff treated with MAD (AHI < 10 w satisfact reduce snoring) Of 19 suff trnd pts, 17 (89.4%) used MAD after 5.2 yrs. 6 of long term titrmt pts had dev replaced w new ones, poor fit, loss of app. 2 of 10 had dev adj then short term & long term visits, this indicates need for prof dent follow up. The pts who replaced, adj dev during study per exp better apnea reduce at long term follow up than pts still using orig dev |
| Author | Citation | Question/Review/ Evidence Level | Study Design/Location (type)/Oral Appliance/Rationale/Adjust-tratable/Irritation | Selection Criteria Include (Exclue)/Sample Size/Rationale/| Age/Gender/| Outcomes AHI / Oz Sat /ESSI/ Other/| Categorical Tx-Snooring /Other/Predictors | Internal Bias // External Bias | Reviewer Comments | Study Conclusion |
|--------|----------|----------------------------------|-----------------------------------------------|-------------|---------|-----------------|-----------------|-----------------|-----------------|----------------|----------------|
| Markund | New | 1/KF/5 | Comparison to baseline, retrospective/resp monitoring only/MRA, full occlusal coverage, custom, crossover, acrylic/adjustable by MASM-Grp A goal 4 to 6 mm advancement, increased for persisting symptoms, advance measured 4 to 6 mm, anterior open measured: 5mm | Snioring, OSA Severity: severe if they failed CPAP, smoking, dental cheima: class III occlusion, edentulous, arthralgia, myofascial pain, periodontal disease, CSR/K=619. No sample size rationale/m=51 (25-74), 55 yrs (30-75)/49/2(30)/NS/I= 50% decrease in airflow and a >3% desaturation | 277 pts, pre-mean=7 (1.7-74), post-mean=3 (0.7-72), response rate: NS | N/S//N, N, N, N, N/S; loss to follow-up: minimal | patient selection: pts have the appropriate disease; confounding factors: N/A, crossover bias: N/A, errors in ascertainment of exposure: potentially bic completeness with tx based upon self-report, loss to follow-up: minimal; population: yes, it is a large clinical population, intensity: good range of severity | Large study with fairly complete long term follow-up | One of few studies with enough subjects to determine predictors of outcome |

Mayer | 65 | 1.2/WSN/5 | Case series, comparison to baseline, prospective/retrospective /sleep lab (full PSG, attended)/MRD- Esmarck device, partial, custom/| OSAS severity AI > 30, dental criteria (>20 + 55, 55/1, 85/NS) M=24, F=6 // BMI 31.7 // NS | N/S//N, N, N, N, N/S; OSA: N=129 (54% success, AHI > 10), 122 severe OSA: 44% (39% success), 219 OSA: 15% (72% success)/lower AHI, demographic: female, other: more advancement, Poorer outcome: weight gain, nasal obstruction | N/S/NS // CATEGORY MISSING | patients have appropriate disease // pop generalize | Data showed no significant difference between control & apnea patients with regard to import cephal landmaks, ant "apnic skull" not found, cephal: narrower SNA angle, wider SNA angle & shorter the uvula, the more effect the device |

McGown | 101 | 3.4/KF-RG/5 | Retrospective case series, consecutive pts /subjects/sleep lab (PSG, attended)/NS/IMFD: 2 diff MASM-Grp A Silencer (full, custom) or Grp B Herbst (full,custom)/both adjustable/prot def: usual clinical protocol/ not described | Sniors or OSA-mild, sex, consec pts treated at Royal London Hosp, Middlesex Hosp between 1984 & 1997 // Sleep lab (PSG, attended)/NS/NS/NS/140 M, 26F/NS/NS | N/S/NS/NS/Pain: discomfort, min-temp: 25 of 69 users, 24 non-users, TMJ: 26 of 69 users, 21 non-users, Oc changes: 9 out 69 users, 2 non users, Other: excess saliva, 7 of 69 users, 13 non-users, 4% others had SE's nightly, subs who stopped had more SE's: 57 of 126 (45%) stopped appliance (29 side effects, 12 poor efficiency) | N/S/NS/NS/Other: Vigilance Test, grp N=30/ prevalence of 7.6 (12.1), post-meal mean 3.7 (6.8), p=0.01; regression analysis indicates a better result with Ed in patients with prognathic maxilla, retrognathic mandible, lower tongue base, shorter uvula, small retropalatal space/NS | N/S/NS // CATEGORY MISSING | patients have appropriate disease // pop generalize | Some hesitation, protocol not defined well | Data showed no significant difference between control & apnea patients with regard to import cephal landmarks, ant "apnic skull" not found, cephal: narrower SNA angle, wider SNA angle & shorter the uvula, the more effect the device |

Mehta | 56 | 1.2.4.5/ KF-RC/2 | Random crossover placebo control trial/sleep lab (full PSG, attended)/MRD, full, custom/yes to advanced to max tolerated protrusion over 19.7±8.8 wks (range 5-40 wks)/mean advance 7.5 ± 1.8 mm (78% of max protrusion), ant opening 3-4 mm | Snioring, OSA severity, AH≥10 per hr, 3 2 symptoms of OSA (dental criteria - edentulous, periodontal disease, exag gag reflex, regular sedative use)/sample size of 30 for power of 0.8 and 0.05<0.05(48 ± 9 range 35-75/M=19, F=5/29/3.4 ± 24 8.3-6.3)/ ≥50% reduction in airflow or thoracoab movement, 10 sec < a desat ≥ 23% or arousal | N/S//NS/NS/NS/Pain: discomfort, min-temp: 25 of 69 users, 24 non-users, TMJ: 26 of 69 users, 21 non-users, Oc changes: 9 out 69 users, 2 non users, Other: excess saliva, 7 of 69 users, 13 non-users, 4% others had SE's nightly, subs who stopped had more SE's: 57 of 126 (45%) stopped appliance (29 side effects, 12 poor efficiency) | Gripp Users, self reported snores improved 0.9% success, Grp users, 39% success/Daytime symptoms: self report improvmt ≥50%, Grp users 64% success, Grp non users 33% success/SE's increased rate of stopping, less snoing and improved symptoms more likely to use | Gripp Active: pre-mean AHI 26 ±15, post-mean 14 ± 2, 46% decr; grp Placebo pre-mean 26 ± 19, post-mean 30 ± 2, 15% incr; p<0.001 b/w active and placebo grp at outcome/Gripp Active: Min SaO2 pre-mean 87 ± 1, post-mean 91 ± 1.3% incr; p<0.001 b/w active and placebo-group at outcome/Gripp Active: EGG pre-mean 10.1 ± 1.1, post-mean 3.9 ± 0.6, p<0.01, Gripp Placeo/NS/Other: Snioring Eq/pe/ grp Active post-mean 242 ± 28, 47% decr, grp Placebo post-mean 452 ± 29, p<0.005 b/w active and placebo grp at outcome/Snioring: mean snoring intensity, DB, Gripp Active post-mean 49 ± 9; Gripp Placebo 52 ± 1, p<0.001 b/w active and placebo grp at outcome/Snioring, mean snoing intensity, dB, Gripp Active post-mean 68 ± 1, gpt Placebo post-mean 70 ± 1, p=NS b/w active and placebo grp at outcome/Arousal index grp, Active post-mean 27 ± 2, 34% drop, Gripp Placebo post-mean 41 ± 2, p<0.001 b/w active and placebo grp at outcome/subjective reports - Gripp Active 70%, success, 30% fail/Complete success resolution of symptoms & AHI < 5 per hr; partial response; improve symptoms & AHI reduced ≤ 50% but AHI staying over 5 per hr, Tx failure: ongoing symptoms &/or not reduced by 50%, Compliance failure, inability to use the tx. Gripp Complete= N success = 9, 37.5% success; Gripp Partial success = 6, 25% success; Gripp Failure = 2, 37.5% fail; Sleep Quality, Gripp Active 91% success, 9% fail, Gripp Placebo NS?//Predictive equation for postRx AHI: Neck circumference baseline AHI (high NC or high AHI - Higher AHI postRx) ± 2 cephal measurements | Subjective reports - Gripp Active 70%, success, 30% fail/Complete success resolution of symptoms & AHI < 5 per hr; partial response; improve symptoms & AHI reduced ≤ 50% but AHI staying over 5 per hr, Tx failure: ongoing symptoms &/or not reduced by 50%, Compliance failure, inability to use the tx. Gripp Complete= N success = 9, 37.5% success; Gripp Partial success = 6, 25% success; Gripp Failure = 2, 37.5% fail; Sleep Quality, Gripp Active 91% success, 9% fail, Gripp Placebo NS?//Predictive equation for postRx AHI: Neck circumference baseline AHI (high NC or high AHI - Higher AHI postRx) ± 2 cephal measurements | Yes, No, No Crossover bias, None, Few dropouts and they were considered compliance failures /Typical OSA patients with good severity range | Calc time in supine sleep, did not analyze effect of supine on AHI w MAS, NC at online data supplement; binding not mentioned | Well-done randomized placebo controlled crossover study - 62% had complete, or partial response in patients with moderate to severe OSA
Mein 57 1.2,3/WISN/5 Case series, comparison to baseline/ sleep lab (full PSG, attended)/MWT/IMR, partial, custom/NS/INS OSA pts - OSA severity RDI >10 plus 2 symptoms of ESS>10, am h'ache, snoring, nocturnal choking, > 18 yrs (dental contraindications, other sleep disorder, signif comorbidity, CSA)//NS//47.7±10.1//18M, 1F//31.9 ±4.6//NS

Outcomes AHI // O2 Sat //ESS //Internal Bias // External

GiP N=23, premean 37.2±10.2, postmean 18.2±2.1, p=0.01; GiP N=23, premean 78.0±8.1, post 86.0±5.6, p=0.05//NS/ MWT GiP N=13 premean 25.9±5.8, postmean 19.8±2.6, p<0.05//CEPH, GiP PAS, premean 4.0(1.6), post mean 6.8(3.8), p<0.01; GiP MP-H, premean 26.6 (8.1), costmean 17.8 (8.4), p<.001 / pain, min-temp, discomfort

NS/ RDI Success = 50% better + RDH=20, N Success = 16, N fail = 7, RDI Success = RDI < 10, N success =12, N fail = 7

Patients have appropriate disease, no crossover bias (pop generalize-OSA)

Cephs meas: non of stand cephs meas sig correlated with changes in RDI, O2 sat nadir, or MWT

MWT mean sleep latency

NS/ NS/CATEGRY MISSING

MWT is useful in the long-term treatment of pts with mild/moderate OSA

Milman 59 1/WISN/5 Case series, comparison to baseline/ sleep lab (full PSG, attended)/IMR- Herbst, full, custom/yes wear until comfortable OSA patients with UPP + OA - OSA severity RDI >10 + NS ) // No 42 // M=17, F=1, BMI 29.3 // airflow <50% plus arousal OR 2% desat

Outcomes AHI // O2 Sat //ESS //Internal Bias // External

GiP N=18, pre-mean 37.2(7.1), post-mean 15.3 (4.4), p=0.01 // N=18, pre-mean 83.9 (1.6), post-mean 87.9 (1.2) p<0.05 /NS/INS/INS

NS /NS CATEGORY MISSING

Patients have appropriate disease, confirming factor UPPP + OA generalize- to OSA + UPPP, mild to severe intensity

NS

OA appears to be an effective mode of therapy to control OSA after unsuccessful UPPP

Neill 104 1.4/KP-KR/5 Case series, comparison to baseline/ sleep lab (full PSG, attended)/IMAS custom, partial/No/attempted to get 75% max protrusion, end point criterion comfort, 75% protrusion, ant opening measured 11mm average

Outcomes AHI // O2 Sat //ESS //Internal Bias // External

GiP all, pre mean RDI 22.2±19.8, post 16.5±2.4, 16% decr, p=0.03; GiP all supine RDI, 30.8±23.8, post 18.8±22.1, 39% decr, p=0.01//NS/GiP all ESS pre mean 12.2±4.8 post 10.4±7.5 14.4% decr, p<NS/Other/snorin. GiP all premean aver snore level 52.7±4.1, post 50.7±2.7, 3.8% decr, p<0.05; GiP All Group RDI 3.4±7.5, post 6.4±2.4, 10% decr, p<NS/15 of 19 (79%) had SE - minor - pain, teeth, gums, x saliva snoring, choking, unable to keep in mouth, in 5 (19%) 26% SE prevented regular use

Snoring by partner report on Likert scale mean improvement 50.8 ±27%, p<0.01/other: GiP All 41% complete success (RDH=5), GiP All 58.5% partial success (RDH=10 but ≥50% reduction). GiP All 71.67% failure (RDH>5) and 50% reduction/Other: improved sleep quality 28 ± 23%, p<0.001; other: improved daytime alertheness by 22±24%, p<0.01/no predictors not age, bmi, initial RDI or positional OSA

GiP all: n success = 16, n fail = 7; RDI Success = RDI <10, N success =12, N fail = 7

Patient selection bias: no; Crossover bias (order effect): Randomly assigned to first of last part of night with MAS; Errors in ascertainment: used the device during the follow-up study; Loss to follow-up: No;Population: probably generalizable; Intensity: Mild to severe – good range

MAD reduces collapsibility of the upper airway in sleep objectively. Small study, Not an appropriate way of measuring AHI, used 2 appliance types, (1 in 16 pts), the other in semidentate and edentulous patients

Patients have appropriate disease RDI 10+ ( NS) // No //42.7 // M=17, F=1// BMI 29.3 // airflow <50% plus arousal OR 2% desat

The MAS improves objective and subjective indices of OSAS and snoring. Side effects were common and in some cases prevented regular use. MAS is a viable alternative to CPAP. Reliance on subjective response may be misleading

MAD reduces collapsibility of the upper airway in sleep

NS/ NS, NS, NS, NS, NS/population likely generalizable, intensity range from mild to severe OSA

Largely a mechanisms paper, shows that oral appliances decrease upper airway collapsibility, greater the decrease in collapsibility the greater the improvement in AHI

MAD reduces collapsibility of the upper airway in sleep

O'Sullivan 62 1.2/WISN/5 Case series, prospective, comparison to baseline/ sleep lab (PSG attended)/MAS, full occl cov, custom/titratable/yes/titrated to max comfortable limit, adv measure: 4.6±1.4mm

Outcomes AHI // O2 Sat //ESS //Internal Bias // External

GiP all: pre AH1 25.0±8.8, Post AH1 13.2±2.0, 47% decr, p=0.03/Low SaO2 mean SEM 86.4±4, Post SaO2 5.9±3% incr, p<0.01/NS/Upper Airway Collapsibility (UACP) ST2 NREM pre mean SEM -1.6±1.4 post -3.9±1.9, 44% decr, p<0.01; other: Upper Airway collapsibility: (UACP) ST2 NREM pre mean SEM -2.5±1.9 post SEM -4.7±1.7 88% decr, p<0.01/AE: mild side effects x saliva snoring, gum irritation, mouth dryness, jaw discomfort

NS/all: n success = 7 (70%); n failed=3 (30%); 6 (60%) AHI <10; complete response(CR) AHI<5 + symptom resolution (5, 50%).  Partial response-improved symptoms plus a >50% reduction in AHI but AHI > 5 (20%), Failure < 50% reduction in AHI (3, 30%) Amt of mand protrusion did not correlate with chan of the upper airway in sleep effect): Randomly assigned to first of last part of night with MAS; Errors in ascertainment: used the device during the follow-up study; Loss to follow-up: No;Population: probably generalizable; Intensity: Mild to severe – good range

When A+HI < 60 MAS can be acceptable treatment

MAD reduces collapsibility of the upper airway in sleep

Ono 63 1.2,6/WISN/5 Case series, comparison to baseline, case series with cross-over, compare to baseline and all rx, randomized to order /sleep lab (full PSG, attended)/IMR, partial, semidentate and edentulous patients/ (TRD- 2 types /No /INS)

Outcomes AHI // O2 Sat //ESS //Internal Bias // External

GiP TRD-A: pre-mean 11.1 (7.8), postmean 5.8 (2.4), p<0.05; GiP TRD-B: pre-mean 11.7 (5.0), postmean 5.8 (2.4), p<0.05 //NS/INS

NS/NS CATEGORY MISSING

Patients have appropriate disease/ generalizable - select patients, variable intensity

Reviewers Comments

When AH1< 60 MAS can be acceptable treatment

TRD improves AH1 after 6 months
### Table of Research Findings

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<td>1.4.6/KF-RC/7</td>
<td>Case series, comparison to baseline, prospective/LAB (PSG, attended)</td>
<td>Snoring and OSA mild to severe, oral appliance used</td>
<td>Errors in ascertainment</td>
<td>Satisfactory or moderately satisfied = success, population: likely generalizable, intensity: good range of OSA severity</td>
<td>An adjustable MAD (the TAP) is effective treatment for snoring in most patients and improves OSA in many patients. Higher BMI better.</td>
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<td>Panin 68</td>
<td>3.4/KF-RC/7</td>
<td>Case series, retrospective, observational /dental office /NS/IMReD-MAS/NS/SE</td>
<td>Snoring &amp; OSA mild, oral appliance</td>
<td>NS, NS, NS, NS, NS</td>
<td>Satisfactory or moderately satisfied = success, likely generalizable, intensity: good range of OSA severity.</td>
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<td>Pellanda 70</td>
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<td>Case series/lab (PSG, attended)/NS/IMReD-Serenox, partial Joint Comm, custom/NS/appliance set at near max protrusion</td>
<td>Snoring &amp; OSA mild (AH1&gt; 20 unless CPAP failure)</td>
<td>NS, NS, NS, NS</td>
<td>Small pre-post study, hard to compare median values to other studies, effective appliance.</td>
<td>Improved snoring and OSA with the oral appliance.</td>
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<td>Petelle New</td>
<td>8/KF/7</td>
<td>Case series, comparison to baseline, prospective/ ?(full PSG, attended)/MRA, full, custom/NS/2 consecutive nights of PSG-one for titration of the appliance and one with the MRA set at the therapeutic position, adv measured: 12.6a 2.7 (120% of mx protrusion)</td>
<td>Snoring/OSA(severity, All were CPAP failures inadequate teeth, TMJ prior UPPP)</td>
<td>NS, NS, NS, NS, NS</td>
<td>Small pre-post study, likely generalizable, intensity: good range of OSA severity.</td>
<td>Improved snoring and OSA with the oral appliance.</td>
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<td>Piss 56</td>
<td>1.2.6/WSN-RN/1</td>
<td>Randomized controlled trial, compare to placebo group, compare to alternative treatment group/lab (PSG, attended)/No/IMReD: 4, 14mm opening, full occlusal, custom/NS/prot def: yes, adv meas: yes, ant open space: yes</td>
<td>OSA-sev: AH1&gt; 15 per hr, dent cndt: adequate dentition, ≥6mm mand adv, no period dis or decay, no TMJ, other-adequate nasal airflow/NH=15 no rational/30-60 yrs median (32-74) 10 M, 4/F/28.9 median (20-40)</td>
<td>NS, NS, NS, NS</td>
<td>Accept-not necessarily for the ET but should be included b/c it describes an overnight titration protocol for MRA</td>
<td>No transverse or vertical movement, results should be similar to MRA.</td>
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### Study Design

- **Type of Study:**
  - Prospective
  - Retrospective
  - Observational
- **Sample Size Rationale:**
  - Age
  - Gender
  - BMI
  - Hypopnea
- **Selection Criteria Include:**
  - Exclude
  - Location (type)
  - Sample Size
  - Oral appliance
  - Adjust-titratable
  - Titration
- **Outcomes AH1:**
  - O2 Sat
  - ESS
  - Internal Bias
  - External Bias
- **Reviewer Comments:**
  - Yes
  - No
- **Study Conclusion:**
  - Large study with nearly complete clinical follow-up - but significant number of patients without PSG follow-up. Success (decrease in AH1) inversely related with BMI. Higher BMI less percentage decrease in AH1. Improved snoring and OSA in many patients. Higher BMI shown. Improved snoring and OSA with the oral appliance.
Randerath X09 1/RF/2

NS/sleep lab/full PSG, attended/IMRA, activator, partial, custom/not described/not well described, anterior opening measured: 12 mm

CPAP more effective, ISAD not titrated. Sub-optimal result with ISAD/20/95.5 ± 10.2/16/4MF/NA/Reduction of ± 50% in airflow > 10 sec or reduced flow and effort with a 4% desat

AHI, ISAD, pre mean=17.5 ± 7.7, post mean= 13.8 ± 11.1. AHI, CPAP, pre mean= 17.5 ± 7.7, post mean=3.2 ± 2.9/02. ISAD pre=83.8 ± 4.6, post=85.3 ± 3.1. AHI, CPAP= pre=83.8 ± 4.6, post= 89.3 ± 3.4/4INA/Arousal Index, ISAD, pre=21.8 ± 9.9, post=17 ± 5.1. CPAP, pre=21.8 ± 9.9, post=14 ± 5.1. Snoring (snore per hour). ISAD, pre=54.5 ± 26/hr, post=36.4 ± 17.7. CPAP, pre=54.5 ± 26. p=post=10.3 ± 5.0/NS

N/S!!Success AHI > 10, ISAD, success=6, fail=14. CPAP, success=20, fail=0/no AHI, younger age better result

CPAP more effective. ISAD not titrated. Sub-optimal result with ISAD

Robertson 73 4/WSN-RP/15

Case series, comparison to baseline, observational study, consecutive subjects, prospective, evaluators not blinded/IMRA, full occ cov, custom/not adjustable/end pt crit: 75% of max protrusion

Snoring, plus medical referral, use 7 nights/wk, 5+hr/night (EXCLUDE MISSING) // SSR MISSING/type 48/8/9//87TM, 13FM/BI & HYPOPNEA MISSING

N/S/NS/NS/Other Cephalogram shows that maxillary incisors retrocline, mandibular incisors proclined; changes appear at 12-24 months/?? MISSING CATEGORY

N/S/NS/No Internal validity: no bias/external validity: sample typical of a OA users referred to a dentist and OSA

Unique study of effect of OA use on tooth position shows a systematic change in incisor inclination over 12-24 months of OA use

Robertson 111 3.4/RF/15

Case series, comparison to baseline, no consecutive subjects, prospective/IMRA, full, custom, rigid splint/non-adjustable/Protocol defined: splint set at 75% of maximum protrusion/protrusive range measured: max protrusion 3 to 14 mm; end point criterion: advance measured: -6.83 +/- .8 mm, anterior opening measured: 5.64 +/- 1.86 mm

Snoring, mild to moderate OSA, had to be wearing MRA 5-6 hrs/night, 7 nights/week (NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)/(NS)
OSA is a common sleep disorder characterized by episodes of partial or complete airway obstruction during sleep, resulting in disrupted sleep and various health consequences. The Apnea-Hypopnea Index (AHI) is a measure used to quantify the severity of sleep apnea, with higher values indicating more severe sleep apnea.

The documentation provided contains a detailed analysis of a case series involving the use of a mandibular advancement device (MAD) to treat obstructive sleep apnea (OSA). The study aimed to evaluate the outcomes of MAD treatment in patients with OSA, with a focus on the AHI and other relevant parameters such as oxygen saturation (SpO2) and the Epworth Sleepiness Scale (ESS). The study design included a comparison of MAD treatment to placebo and baseline conditions to assess the effectiveness and safety of the device.

Key findings from the study include:
- AHI and oxygen desaturation indices (ODI) were lower for the MAD group compared to the placebo.
- The MAD was less successful in patients with severe OSA (AHI > 50).
- Compliance was excellent, and complications were mild.
- The MAD was adjusted on follow-up to optimize treatment success.

Overall, the results suggest that MAD treatment can be effective in managing mild to moderate OSA, with a need for individualized adjustments to achieve optimal outcomes.

The study also highlights the importance of integrating multidisciplinary approaches, including dental, orthopedic, and psychological interventions, to provide comprehensive care for OSA patients.

In conclusion, the use of MAD devices in OSA management is promising, offering a non-invasive and potentially less invasive treatment option compared to conventional therapies such as continuous positive airway pressure (CPAP). Further research is needed to understand the long-term effects and sustainability of MAD treatment, as well as to explore the role of other non-pharmacological interventions in managing OSA.

Author: Rose
Institution: KF
Study Design: Case series, comparison to baseline, retrospective
Comparison: MAD vs. placebo
Outcome Measures: AHI, oxygen saturation (SpO2), Epworth Sleepiness Scale (ESS)
Sample Size: 81
Results: MAD was less successful in patients with severe OSA (AHI > 50).
Compliance: Excellent
Complications: Mild

The study emphasizes the importance of adjusting treatments based on individual patient responses and maintaining follow-up to ensure continued success.
Trailing

Study Design/Location (type)/Oral Appliance/Adjust-titratable/ Titrations

Selection Criteria include (Exclude)// Sample Size Reasonable// Age/Gender/BMI/Headache

Outcomes AHI // O2 Sat //ESS// Other/Other

Categorical Tax-Snorong //Other/Other/Other

Internal Bias // External

Reviewer Comments

Study Conclusion

MISSING INFORMATION

Well-done study with objectively documented benefit on snoring with secondary benefit of better breathing

Tulini X01

1, 2/WSN/5

Case series, comparison to baseline, subjects, prospective/iv respiratory monitor, unattended in home, oximetry, other-PTT// MRD, full occlusal coverage, custom/not adjustable, 75% max protrusion

Snoring, current OA user//

Pre mean=193, post- 20, p<.0001; Snoretime pre- mean 818, post- 50, p<.0002; Sound level pre- mean 7.5, post 2.6, p<.0001; Snoring response=26%; p <.0001 (ODI), 75% group pre=18.0 ± 6.0, response=59.6% ; p<.0001. AHI in responders, anterior velopharynx and posterior hypopharyngeal surfaces are displaced anteriorly; not in non-responders.

Snoring pre-mean=22.9 (6.6) post-mean=0.10(9.1) p<=0.01. Group CPAP: pre-mean=22.9 (6.6) post-mean=3.0 (2.8) p<.001. Other: Snoring improvement no differ between treatments - only in two subjects; 16 of 21 who used both treatments chose the MAS for long-term treatment.

Successful reduction of AHI in OA users is associated with mobility of the airway soft tissues powered study that shows more advancement means more success with OSA MRA tx

Internal validity: no bias; external validity: patient selection restricted to OSA patients selected for OA therapy

Successfull reduction of AHI in OA users is associated with mobility of the airway soft tissues

Well-done adequately powered study that shows more advancement means more success with OSA MRA tx

Walker-Engstrom New

1/5K/1

Randomized controlled trial, comparison of an appliance at 2 settings, prospective, blinded evaluators, intention to treat analysis// home, unattended (Resp monitoring only)/MRM, partial occlusal coverage, custom/unadjustable, set at 75% to max protrusion or 50% maximum, end point criterion: adv. measured: 50% group 5.0 mm (4.8 to 5.3) 75% group 7.0 mm (6.7, 7.6) anterior opening measured: 2mm

Severe OSA at >= 30, OA user, no protocol changes; at baseline, NO/yes, set at 75% to max protrusion or 50% maximum, end point criterion: adv. measured: 50% group 5.0 mm (4.8 to 5.3) 75% group 7.0 mm (6.7, 7.6) anterior opening measured: 2mm

75% group: Pre mean= 50.4 ± 4.7, post-mean= 15.6 ± 6.2, responders=69% ; p< .001. 50% group: 47.0 ± 5.1, post-mean= 17.4 ± 6.7, response=63%, p < 0.001/NS (75% group: pre-mean= 11.5 ± 3.1, post-mean= 7.5 ± 2.6, response= 35% ; p=0.001. 50% group: pre-mean= 11.7 ± 3.1, post-mean= 8.6 ± 2.8, response=26% ; p < 0.001 (ODI), 75% group: pre-mean= 49.7 ± 5.6, post-mean= 19.1 ± 7.0, response=24% ; p < 0.001 OD1-50% group: pre-mean= 18.0 ± 6.0, response=59.6% ; p< 0.001, AHI in responders, anterior velopharynx and posterior hypopharyngeal surfaces are displaced anteriorly; not in non-responders.

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Well-done adequately powered study that shows more advancement means more success with OSA MRA tx

Strading 1/WSN/RRR

Case series, comparison to baseline, subjects, prospective/iv respiratory monitor, unattended in home, oximetry, other-PTT// MRD, full occlusal coverage, custom/not adjustable, 75% max protrusion

Snoring, current OA user//

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Fan 1/WSN,RRR

Case series, comparison to baseline, subjects, prospective/iv respiratory monitor, unattended in home, oximetry, other-PTT// MRD, full occlusal coverage, custom/titratable/yes, end point criterion: symptoms, adv measured: 85-80% of max protrusion, anterior opening:2mm

OSA/severity, dental criteria(dental criteria)//N=18/age 45.9/15M:18F/BMI 27.7(5.4)/

NS/NS//No apparent order effect, two-week wash-out //NS//Minimal loss to follow-up//generalizable//good range of severity

Internal validity: no bias; external validity: patient selection restricted to OSA patients selected for OA therapy

Successfull reduction of AHI in OA users is associated with mobility of the airway soft tissues

Well-done adequately powered study that shows more advancement means more success with OSA MRA tx

Tsuzuki K F 1/WSN/31

Case series, comparison to baseline, subjects, prospective/iv respiratory monitor, unattended in home, oximetry, other-PTT// MRD, full occlusal coverage, custom/titratable/yes, end point criterion: symptoms, adv measured: 85-80% of max protrusion, anterior opening:2mm

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Wilhjemson plus SE from Tegelberg #84 and Q of Life from Walker-Engstrom #88 (and Ringqvist (X02) and WalkerEngstrom #89).

RCT, prospective, comparison to baseline & alternative Rx (UPPP)/*Home (respiratory monitoring only, unattended)*/ MAD, full occlusal coverage, custom, No/ No/ Protocol defined: set ≥ 50% max protrusion (4-8mm), anterior opening measured: 5mm intercissal

N=1,3,5,7-KF-WSN-RC-RN/1

MAD patients: pre mean AHI= 18.2 (15.7 - 20.8 95% CI), post mean AHI = 5.8, -12.4 response, p<.001; UPPP grp pre mean= 20.4 (17.4 - 23.3 95% CI), post mean=10.4, 51% response, p<.001; UPPP patients improved in AHI & 61% success, Grp UPPP 26 of 43 completers (60%), 26 out 46 rand (57%), GRP completers - MAD better reducing AHI by 50%; intention to treat no diff! Other compliances - Tegelberg #84 73% and with UPPPNNS: no difference in sleepiness at baseline between grps at 12 months no difference between grps, but did differ in OA group: pre mean 0.7 (6.8-9.5% CI) post mean 0.5, -1 response; UPPP grp: pre mean 1.7 (7.8-9.5% CI) post mean 0.5, 95% CI, post mean 5.5, -8.4 resp, p<.001; Greater in AHI & 61% success in AHI & 61% success in OA, AHI < 5; NS (NS)

Large prospective random study showing that OA is more effective than UPPP. Fours year use of OA with limited mandibular protrusion (50% max) and partial dental coverage (molars) produces no significant dental or skeletal change. Good long-term outcomes in OA group.

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<td>1</td>
<td>Yoshida</td>
<td>95</td>
<td>1.2/WSN-RR/5</td>
<td>Case series, comparison to baseline/lab</td>
<td>OSA-sev (NS) NS/ mean 57.7 yrs/ 1 F, 19 M/ NS/ NS</td>
<td>Gip 1 pre mean 57.2 (21.1), post mean 25.8 (29.3), p&lt;.0001/ NS/ NS/ Other correlation of AHI decrease w mand jaw length, soft palate length (inverse)/ Cranio fact: mand jaw length, soft palate length/ NS</td>
<td>NS/NS CATEGORY MISSING</td>
<td>Patient selection: yes/ Population: no, inadequate descrip, intensity: variable/ NS</td>
<td>Effect size estimated and outcome measures extensive</td>
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<td>2</td>
<td>Yoshida</td>
<td>X07</td>
<td>1.0/RR/5</td>
<td>NS/sleep lab (full PSG, attended)/IMAD, full, custom/No/No</td>
<td>UARS/NS/mean 38.4 yrs/15 F, 17 M/Mean 25.2/NS</td>
<td>All: pre- 3.1 post-1.9/All: pre- 85.4 post- 89.4/All: pre- 13.2 post- 5.8/Arousal (Arousal Index): All: pre- 35.5 post-5.8, Sleep Efficiency: All: pre- 85.4 post- 90.3, MSLT: All: pre- 6.3 post-12.9/NS</td>
<td>NS/NS</td>
<td>Ten patients did not snore originally</td>
<td>MAD is an important treatment option for UARS</td>
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