ResMed

Narval CC™
Mandibular advancement device

Narval CC clinical and scientific research

The Narval CC mandibular advancement device has proven to be an effective treatement for mild to severe OSA, on short[1] and long[4] term follow-up.

ORCADES study (3-6 month follow-up)[1]
Vecchierini MF et al - Sleep Med 2016
- Narval CAD/CAM device seems to be more effective in reducing AHI than non-CAD/CAM Narval device (success rate*: 79% vs 61%)

ORCADES study: Gender data (3-6 month follow-up)[2]
Vecchierini MF & al - Sleep and Breathing 2018
- Significantly higher sucess rate* in women with OSA than in men (89% vs 76%).

ORCADES study (2 years follow-up)[3]
Attali V et al - Sleep Med 2019
- After 2 years, Narval CC continued to have a positive effect on AHI: 67% of patients maintained or improved the AHI scores achieved at 2 years follow-up.

ORCADES study: (5 years follow-up)[4]
Vecchierini MF et al. Clin Sleep Med 2021
- Although there was a tendency for control of the apnea-hypopnea index to decline over time, mandibular advancement device therapy remained effective in >50% of patients after 5 years, with ongoing symptom control, good quality of life, and high levels of adherence and patient satisfaction.

BIOMECANIC study: Compression vs traction-based articulation[5]
Cheze L and Navailles B - ITBM-RBM 2006
- Designed to create on average 10% less stress on the temporo-mandibular joint with traction - based device compared to compression - based device.
- Findings may imply an improved side-effect and compliance profile in clinical practice for traction-based over compression-based mechanisms.

*Success rate: reduction of initial AHI ≥50%

International Clinical practice guidelines and recommendations for the treatment of OSA and snoring

American Academy of Sleep Medicine and American Academy of Dental Sleep Medicine Clinical Practice Guideline.[6]

Standard

- "We recommend that sleep physicians consider prescription of oral appliances, rather than no treatment, for adult patients with obstructive sleep apnea who are intolerant of CPAP therapy or prefer alternate therapy."
- "We recommend that sleep physicians prescribe oral appliances, rather than no therapy, for adult patients who request treatment of primary snoring (without obstructive sleep apnea)."

Guideline

- "When oral appliance therapy is prescribed by a sleep physician for an adult patient with obstructive sleep apnea, we suggest that a qualified dentist use a custom, titratable appliance over non-custom oral devices."
- "We suggest that sleep physicians and qualified dentists instruct adult patients treated with oral appliances for obstructive sleep apnea to return for periodic office visits – as opposed to no follow-up – with a qualified dentist and a sleep physician."
- "We suggest that sleep physicians conduct follow-up sleep testing to improve or confirm treatment efficacy, rather than conduct follow-up without sleep testing, for patients fitted with oral appliances."
- "We suggest that qualified dentists provide oversight – rather than no follow-up – of oral appliance therapy in adult patients with obstructive sleep apnea, to survey for dental-related side effects or occlusal changes and reduce their incidence."

European Respiratory Society Task Force Report recommendations:[7]

- "MADs are recommended for the treatment of patients with mild to moderate OSA and in patients who do not tolerate CPAP. (Grade A)."
- "The device should be custom-made, evaluated and advance the mandible at least 50% of maximum protrusion. A titration procedure is essential."

Sleep Med 2015. DOI: 10.1016/j.sleep.2015.05.020

A custom-made mandibular repositioning device for obstructive sleep apnoea-hypopnoea syndrome: the ORCADES study[1]

Vecchierini MF, Attali V, Collet JM, d'Ortho MP, El Chater P, Kerbrat JB, Leger D, Monaca C, Monteyrol PJ, Morin L, Mullens E, Pigearias B, Meurice JC for the ORCADES investigators.

Objectives

Mandibular repositioning devices (MADs) are usually recommended as the first therapy option in patients with mild-to-moderate obstructive sleep apnoea (OSA). However, data on the long-term efficacy of MADs are limited, not only in OSA patients who are noncompliant with continuous positive airway pressure (CPAP) but also in those with more severe OSA. The ORCADES study aimed to prospectively determine the long-term efficacy and tolerability of two custom-made Narval™ MADs for obstructive sleep apnoea-hypopnoea syndrome (OSAHS) patients. The interim 3- to 6-month data are reported.

Methods

Eligible patients had OSAHS and had refused or were noncompliant with prescribed CPAP. Outcome measurements after gradual mandibular advancement titration included: apnoea-hypopnoea index (AHI), oxygen saturation, sleepiness, symptoms, quality of life, side effects and compliance.

Results

A total of 369 patients were included. Overall, MAD treatment was successful (≥50% decrease in AHI) in 76.2% of the participants; complete response (AHI <10/h) was achieved in 63.5%. Severe OSA was effectively treated (AHI <15/h) in about 60% of the participants; 38% of severe OSA patients had complete symptom resolution (AHI<10). Mandibular repositioning device significantly decreased subjective sleepiness (mean ESS decreased from 11.2 ± 4.8 at baseline to 7.8 ± 4.3, p<0.0001), drastically reduced symptoms and improved quality of life. MAD was well tolerated and the compliance reported was excellent: 6.7 ± 1.3 hours/night, 6.7 ± 0.9 nights/week. Only 8% of the participants stopped MAD treatment due to side effects.

Conclusion

Custom-made Narval™ MADs are effective for mild to severe OSA in patients who refuse or are noncompliant with CPAP. At short term, they are well tolerated and have excellent compliance.

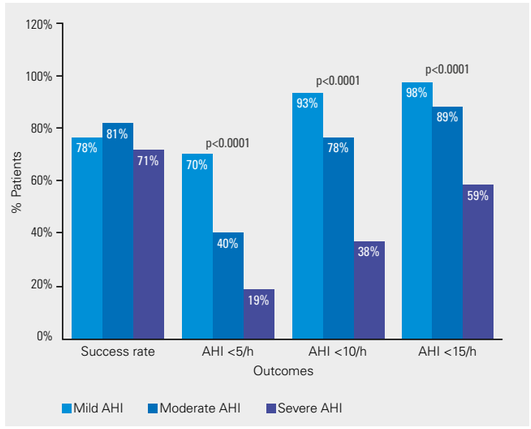

Fig. 1: MAD efficacy by obstructive sleep apnoea – hypopnoea syndrome severity at 3- to 6-month follow-up.

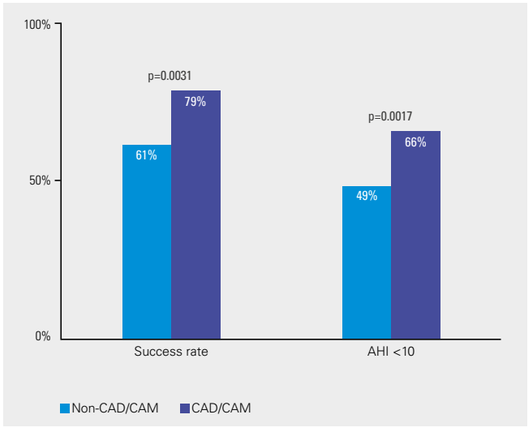

Fig. 2: Efficacy of treatment by type of MAD at 3-6 month follow-up.

Sex differences in mandibular repositioning device therapy effectiveness in patients with obstructive sleep apnea syndrome[2]

Vecchierini MF, Attali V, Collet JM, d'Ortho MP, Goutorbe F, Kerbrat JB, Leger D, Lavergne F, Monaca C, Monteyrol PJ, Morin L, Mullens E, Pigearias B, Martin F, Khemliche H, Lerousseau L, Meurice JC on behalf of the ORCADES investigators.

Objectives

MADs are an effective treatment option for obstructive sleep apnea syndrome (OSAS), particularly in patients who refuse or cannot tolerate continuous positive airway pressure (CPAP). However, sex differences in the response to therapy and predictors of response are not clearly defined. This analysis of data from the longterm prospective ORCADES trial compared MAD efficacy in men and women with OSAS.

Methods

The ORCADES study included patients with newly diagnosed mild-to-moderate or severe OSAS who refused or were noncompliant with CPAP. MAD therapy was titrated over 3–6 months. The primary endpoint was treatment success (≥ 50% decrease in apnea-hypopnea index (AHI)). Complete response was defined using a range of AHI cut-off values (< 5/h, < 10/h, < 15/h).

Results

Overall treatment success rates were 89% in women and 76% in men (p = 0.019); corresponding rates in those with severe OSAS (AHI > 30/h) were 100% and 68% respectively (p = 0.0015). In women vs. men, overall complete response rates at AHI cutoff values of < 5/h, <10/h, and < 15/h were 49 vs. 34% (p = 0.0052), 78 vs. 62% (p = 0.016), and 92 vs. 76% respectively (p = 0.0032). On multivariate analysis, significant predictors of MAD treatment success were overbite and baseline apnea index in men, and neck circumference and no previous CPAP therapy in women. Most of reported side effects were common and not severe. Women who experienced side effects were more likely to discontinue therapy than men (12% vs. 7%, p=0.017). There were sex differences in the occurrence of some side effects (gum irritation). Temporomandibular joint pain was the most common reason for stopping MAD therapy whatever patient gender.

Conclusions

MAD therapy was effective in women with OSA of any severity, with significantly higher response rates compared with men especially in severe OSA.

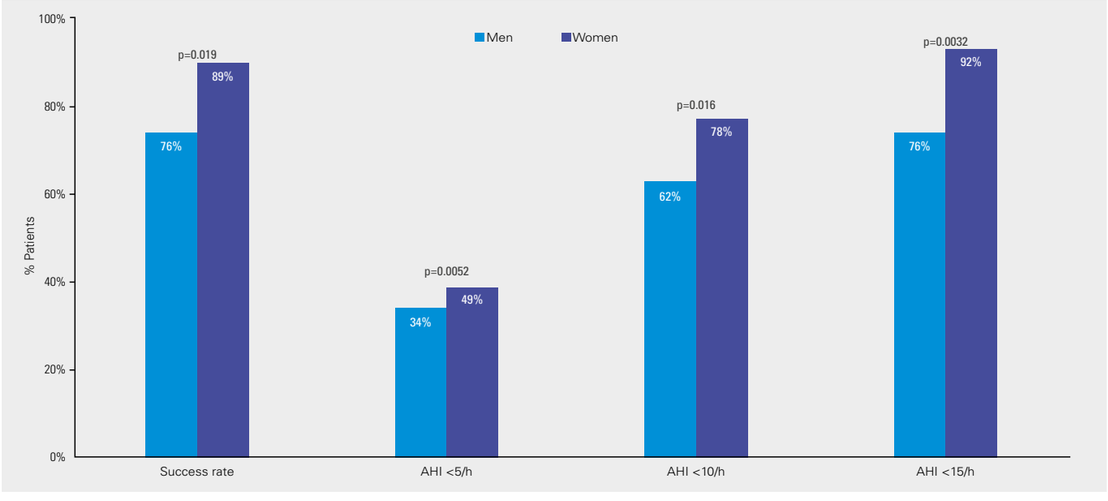

Fig. 1: MAD efficacy in men and women at 3 to 6-month follow-up.

Efficacy and tolerability of a custom-made Narval mandibular repositioning device for the treatment of obstructive sleep apnea: ORCADES study 2-year follow-up data[3]

Attali V, Vecchierini MF,Collet JM, d'Ortho MP, Goutorbe F, Kerbrat JB, Leger D, Lavergne F, Monaca C, Monteyrol PJ; Morin L, Mullen E, Pigearias B, Martin F, Tordjman F, Khemliche H, Lerousseau L & Meurice JC, on behalf of the ORCADES investigators.

Objectives

Mandibular repositioning device (MAD) therapy is an alternative to continuous positive airway pressure (CPAP). The ORCADES study is assessing the long-term efficacy and tolerability of MAD therapy in OSAS; 2-year follow-up data are presented.

Methods

OSAS patients who refused or were noncompliant with CPAP were fitted with a custom-made computer-aided design/computer-aided manufacturing (CAD/CAM) biblock MAD (ResMed, Narval CC™); mandibular advancement was individually titrated. Sleep and respiratory parameters were determined at baseline, 3–6 months and 2 years. The primary endpoint was treatment success (percentage of patients achieving a ≥ 50% reduction in the apnoea-hypopnoea index [AHI]).

Results

Of 315 enrolled patients, 237 remained on MAD treatment at 2 years and 197 had follow-up data. Treatment success rate at 2 years was 67%; AHI <5/h, <10/h and <15/h was achieved in 30%, 56% and 72% of patients, respectively. On multivariate analysis, ≥ 50% decrease in AHI at 3–6 months and absence of nocturia at 3–6 months were significant predictors of MAD treatment continuation. Adverse events were generally mild and the majority occurred in the first year of treatment.

Conclusions

Two years' treatment with an MAD was effective and well tolerated in patients with mild to severe OSAS who refused or were intolerant of CPAP.

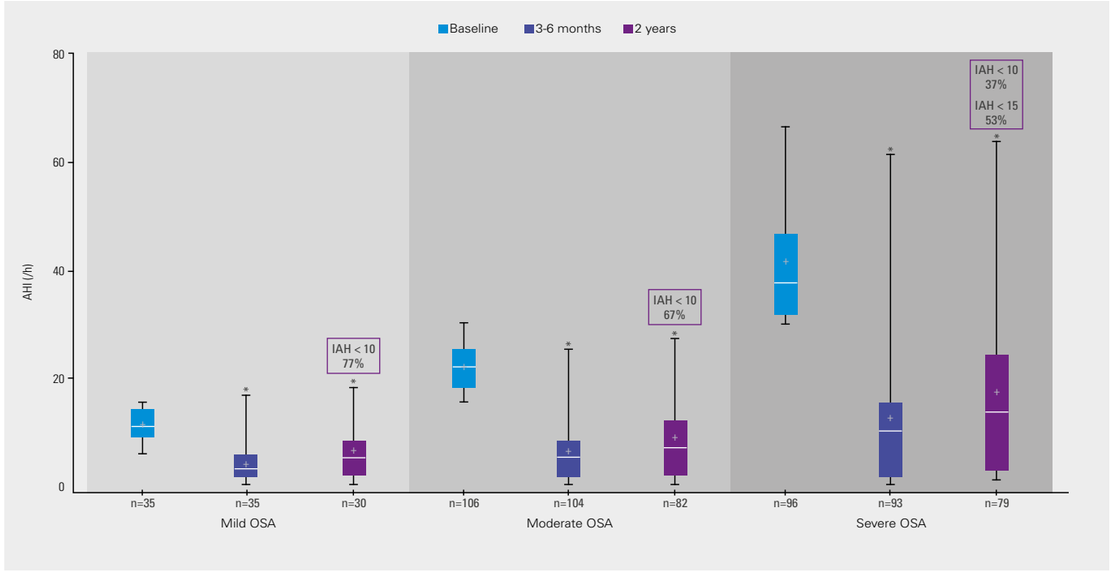

Fig. 1: MAD efficacy at 2-year follow-up by OSAS severity.

J Clin Sleep Med. 2021 May 3. doi: 10.5664

Mandibular advancement device use in obstructive sleep apnea: ORCADES study 5-year follow-up data[4]

Vecchierini MF, Attali V, Collet JM, d'Ortho MP, Goutorbe F, Kerbrat JB, Leger D, Lavergne F, Monaca C, Monteyrol PJ, Mullens E, Pigearias B, Martin F, Khemliche H, Lerousseau L, Meurice JC

Abstract

Mandibular advancement devices (MADs) are an alternative to continuous positive airway pressure for the management of obstructive sleep apnea (OSA). The ORCADES study is investigating the long-term effectiveness of MAD therapy in patients with OSA who refused or were intolerant of continuous positive airway pressure. Five-year follow-up data are presented.

Methods and measurements

Data were available in 172 of 331 patients treated with a custom-made computer-aided design/computer-aided manufacturing biblock MAD (Narval CC; ResMed, Saint-Priest, France). The primary end point was treatment success (≥50% decrease in apnea-hypopnea index from baseline).

Results

Five-year treatment success rates were 52% overall and 25%, 52%, and 63%, respectively, in patients with mild, moderate, or severe OSA. This reflects a decline over time vs 3–6 months (79% overall) and 2 years (68%). Rates declined in all patient subgroups but to the greatest extent in patients with mild OSA. The slight worsening of respiratory parameters over time was not associated with any relevant changes in sleepiness and symptoms. Moderate or severe OSA at baseline, treatment success at 3–6 months, and no previous continuous positive airway pressure use were significant independent predictors of 5-year treatment success on multivariate analysis. No new safety signals emerged during long-term follow-up. The proportion of patients using their MAD for ≥4 h/night on ≥4 days/wk was 93.3%; 91.3% of patients reported device use of ≥6 h/night at 5 years. At 5-year follow-up, 96.5% of patients reported that they wanted to continue MAD therapy.

Conclusion

Long-term MAD therapy remained effective after 5 years in >50% of patients, with good levels of patient satisfaction and adherence.

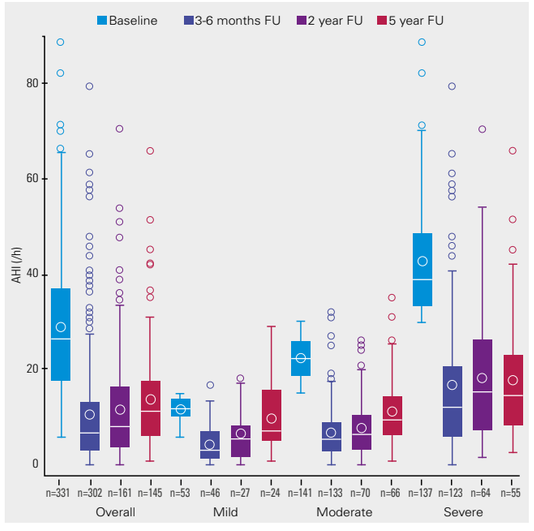

Fig. 1: Change in the AHI over time in the overall population and in patient subgroups based on baseline OSA severity (mild: AHI 5–≤15 events/h; moderate: AHI 15–≤30 events/h; severe: AHI > 30 events/h).

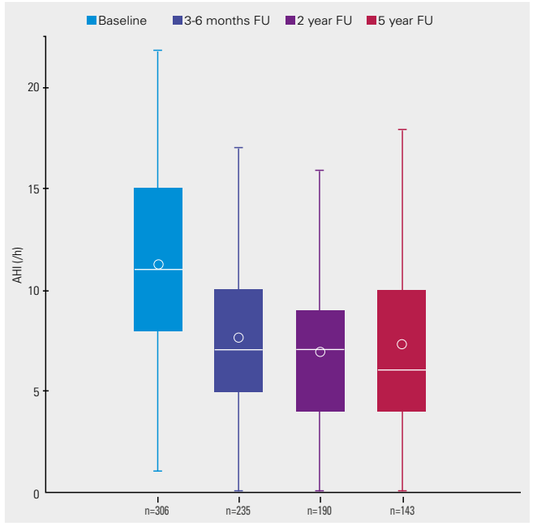

Fig. 2: Change in ESS score during 5 years of mandibular advancement device therapy (P < .0001 for comparison with baseline at each FU visit).

ITBM-RBM 2006;27(5–6):233–237. DOI: 10.1016/j.rbmret.2007.01.004

Impact on temporomandibular joint of two mandibular advancement device designs[5]

Cheze L & Navailles B.

Objectives

Understand mechanical forces applied on the temporo-mandibular joint by two different designs of mandibular advancement devices.

Methods and measurements

Rigid elements model of the temporo-mandibular joint, taking into account six muscles, was developed. A study was designed to compare traction based vs. compression based devices, with mandible in a 10 mm protrusion position. Static equilibrium can be written as hyperstatic equations and resolution is obtained through numeric optimization of different criteria under constraints.

Results

For compression based device, equation results reported that important strength was applied in the masseter and posterior temporal. As both muscles lift the mandible up, this implies mouth opening happens when these muscles were at rest. However, the traction based device enabled 10 mm protrusion with minimal effort on these muscles. Additionally, joint contact strength was consistently less (10%) with traction based device than with compression based device.

Conclusion

This simple mechanical model enables comparison of mandibular advancement devices with different modes of action. The results found are consistent with the ones from literature. Findings on studied parameters (mouth opening, joint contact strength) may imply an improved side-effect and a compliance profile in clinical practice for traction-based over compression-based mechanisms.

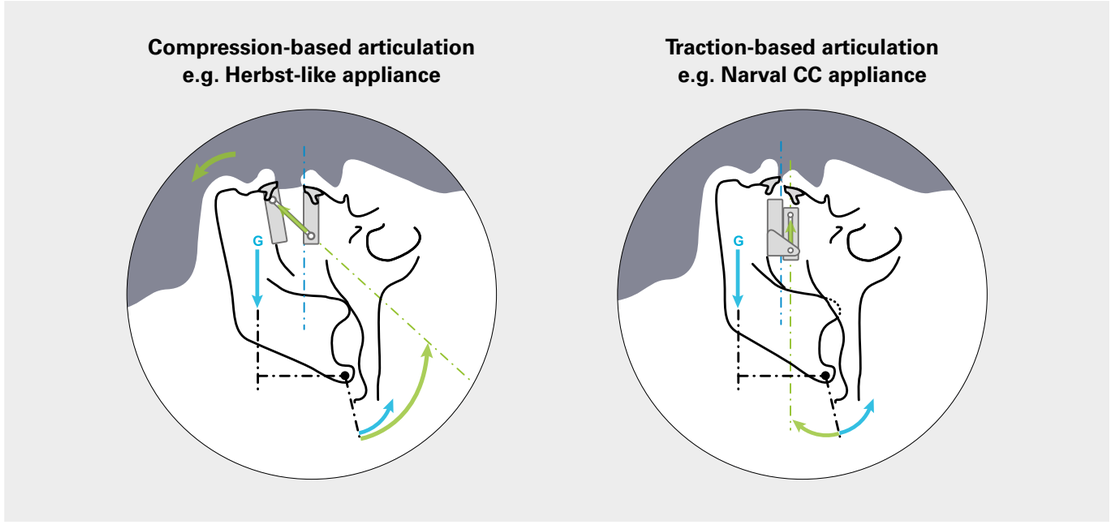

Fig. 1: Diagrams created on the basis of the results from the comparison between compression-based device articulation (left) and traction-based device articulation (right).
The results of the models show that compression-based devices necessarily induce mouth opening when muscles are at rest, which is not the case with the Traction based devices

Please refer to the user guide for relevant information related to any warnings and precautions to be considered before and during use of the product.

1 Vecchierini MF & al. A custom-made mandibular repositioning device for obstructive sleep apnoea-hypopnoea syndrome: the ORCADES study. Sleep Med. 2016 Mar;19:131-40.

2 Vecchierini MF et al. Sex differences in mandibular advancement device therapy effectiveness in patients with obstructive sleep apnea syndrome, Sleep & Breathing 2018.

3 Attali V & al. Efficacy and tolerability of a custom-made Narval mandibular repositioning device for the treatment of obstructive sleep apnea: ORCADES study 2-year follow-up data. Sleep Medicine journal 2019 (in press).

4 Vecchierini MF & al. Mandibular advancement device use in obstructive sleep apnea: ORCADES study 5-year follow-up data. J Clin Sleep Med. 2021 May 3.

5 Cheze et al. Impact on temporomandibular joint of two mandibular advancement device designs. ITBM-RBM, Volume 27, Issues 5–6, November–December 2006, 233-237. Computer simulated biomechanical study.

6 Ramar K et al. Clinical practice guideline for the treatment of obstructive sleep apnea and snoring with oral appliance therapy: An update for 2015. J Clin *Sleep Med* 2015;11(7):773-793.

7 Marie Marklund & al. Non-CPAP therapies in obstructive sleep apnoea - *European Respiratory Journal* - 2011; 37: 1000–1028.