ResMed

Narval CC™
Mandibular repositioning device

Narval CC Clinical Research

The Narval CAD/CAM appliance has proven to be efficient in treating OSA (Obstructive Sleep Apnoea) on both short-term[1] and long-term[2] follow up, with improved side effects and compliance profile. This document contains abstracts and findings from the following research studies:

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

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

ESTAMPS study[5]
Kerbrat A et al - European Respiratory Journal 2018
- Narval CAD/CAM appliances seem to increase oropharyngeal airway volume more efficiently than non-CAD/CAM Narval appliances.

ORCADES study (2-year follow-up)[2]
Attali V et al - Sleep Med 2019
- After 2 years, Narval CC continued to have a positive effect on AHI: 70% of patients maintained or improved the AHI scores achieved at 3-6 month follow-up.

Biomechanical study: compression vs traction-based articulation[4]
Cheze L and Navailles B - ITBM-RBM 2006
- A traction-based device creates on average 10% less stress on the temporo-mandibular joint compared to a 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 [Mandibular Advancement Devices] 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 (MRDs) 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 MRDs 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™ MRDs 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, MRD 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. MRD 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 MRD treatment due to side effects.

Conclusion

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

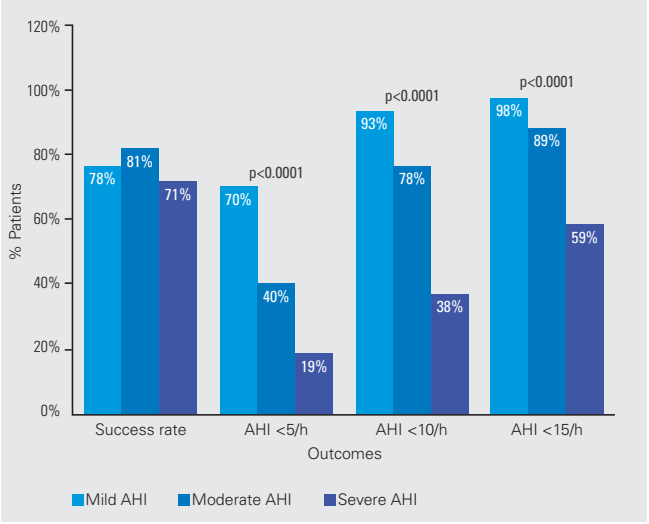


Fig. 1: MRD efficacy by obstructive sleep apnoea – hypopnoea syndrome severity at 3- to 6-month follow-up.

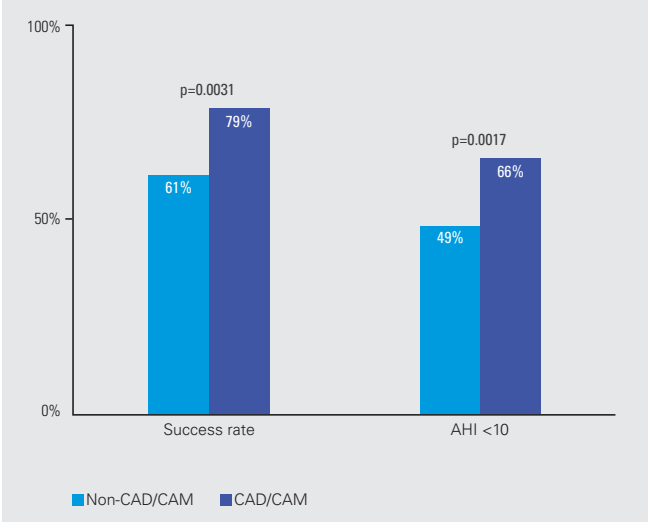


Fig. 2: Efficacy of treatment by type of MRD at 3-6 month follow-up.

Sleep Medicine 2019

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[2]

Attali V, Vecchierini MF,Collet JM, d'Ortho MP, Goutorbe F, Kerbrat JB, Leger D, Lavergne F, Monac 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 (MRD) therapy is an alternative to continuous positive airway pressure (CPAP). The ORCADES study is assessing the long-term efficacy and tolerability of MRD 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 MRD (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 MRD 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 MRD treatment continuation. Adverse events were generally mild and the majority occurred in the first year of treatment.

Conclusions

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

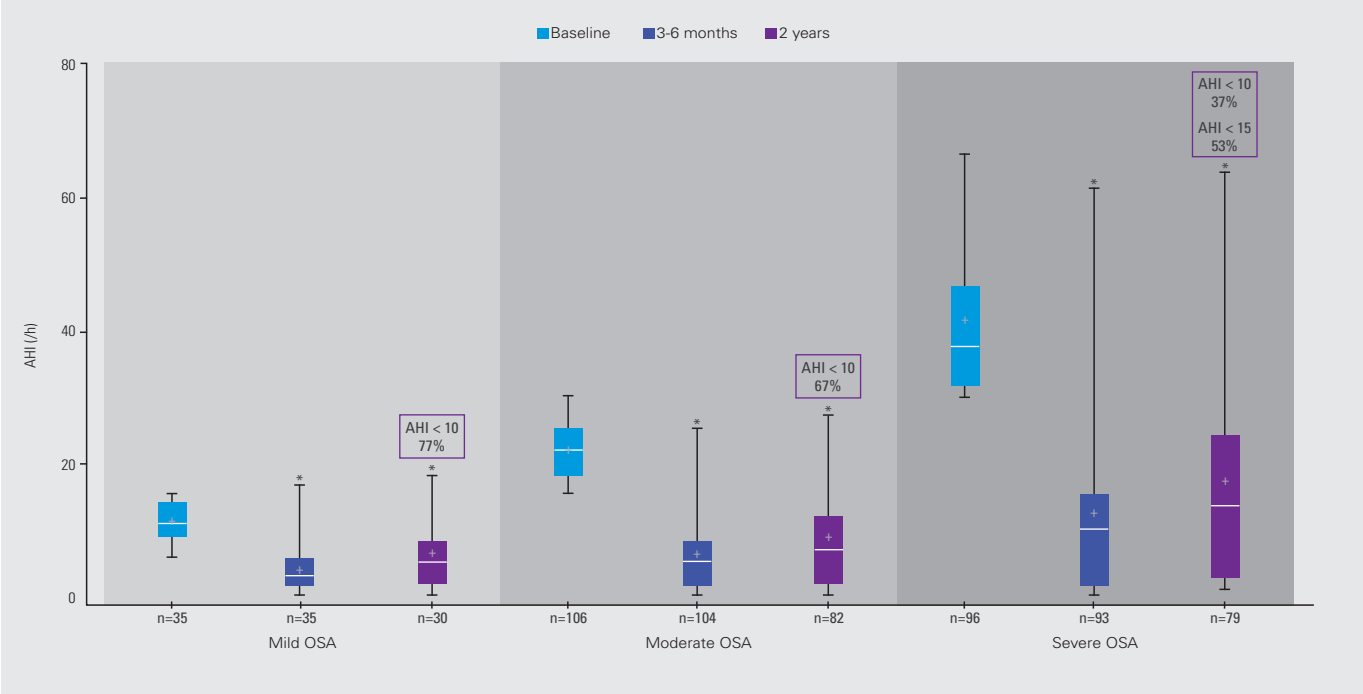


Fig. 1: MRD efficacy at 2-year follow-up by OSAS severity.

Sex differences in mandibular repositioning device therapy effectiveness in patients with obstructive sleep apnea syndrome[3]

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

MRDs 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 MRD 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. MRD 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 MRD treatment success were overbite and baseline apnea index in men, and neck circumference and no previous CPAP therapy in women. Most 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 MRD therapy whatever the patient's gender.

Conclusions

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

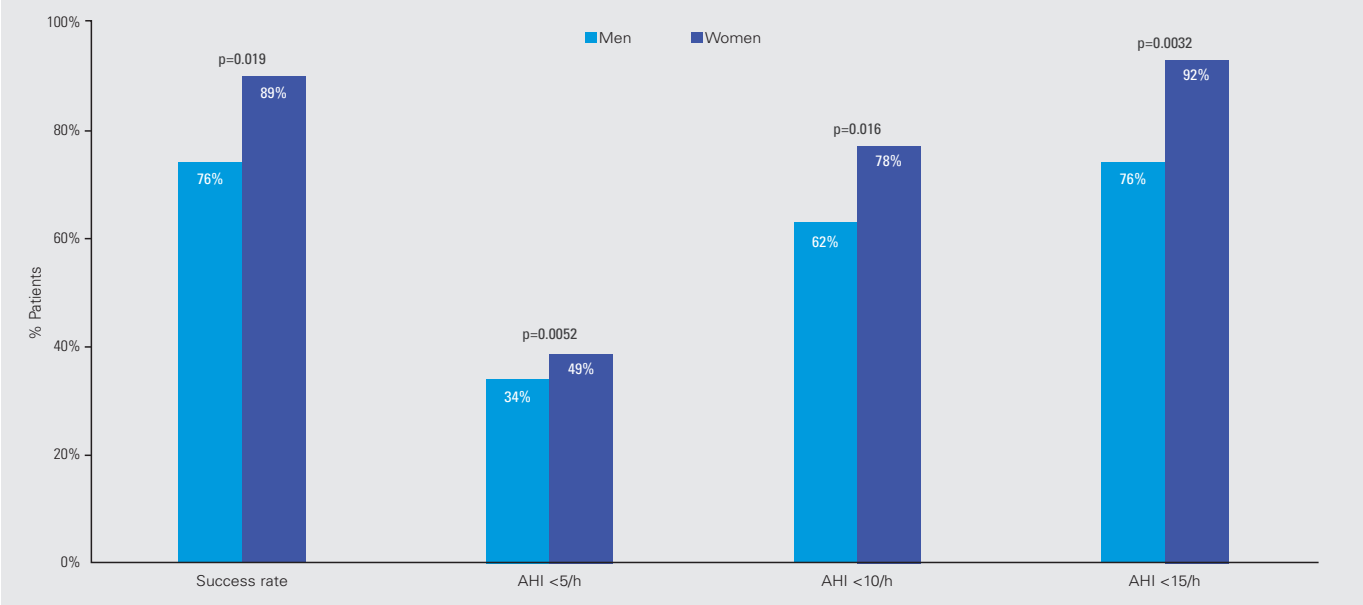


Fig. 1: MRD efficacy in men and women at 3- to 6-month follow-up.

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[4]

Cheze L & Navailles B.

Objectives

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

Methods and measurements

A 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

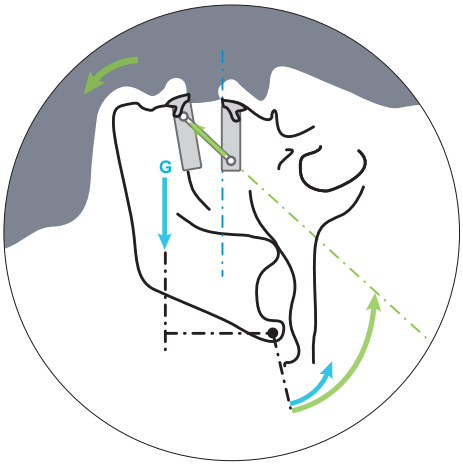
For the compression-based device, equation results reported that significant strength was applied in the masseter and posterior temporal. As both muscles lift the mandible up, this implies mouth opening happens when these muscles are at rest. However, the traction-based device enabled 10 mm protrusion with minimal effort on these muscles. Additionally, joint contact strength was consistently less (10%) with the traction-based device than with the 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 those from the literature. Findings on studied parameters (mouth opening, joint contact strength) may imply an improved side-effect and compliance profile in clinical practice for traction-based over compression-based mechanisms.

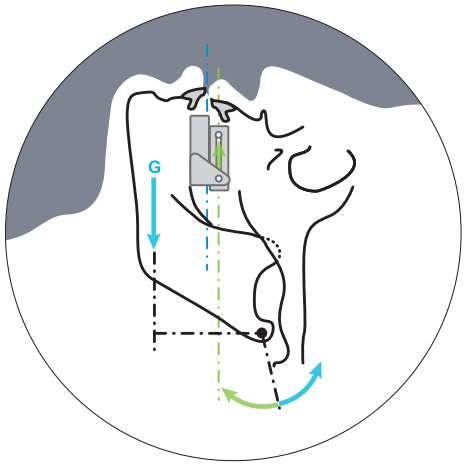
Protrusion-based articulation
e.g. Herbst-like appliance

Tends to provoke mouth opening when muscles are at rest



Retention-based articulation
e.g. Narval CC appliance

Tends to close mouth – counter rotation strength vector will counterbalance gravity



European Respiratory Journal 2018 52: PA4342; DOI: 10.1183/13993003.congress-2018.PA4342

Clinical Impact of 2 types of Mandibular Retention Device (MRD) - Narval CAD/CAM vs Narval non-CAD/CAM – on OSA: ESTAMPS STUDY[5]

Kerbrat A, Vinuesa O, Lavergne F, Aversenq E, Graml A, Kerbrat JB, Goudot P.

Abstract

This pilot crossover randomized study evaluated the impact of 2 custom-made MRD: computer aided design (CAD)/computer aided manufacturing (CAM) (Narval CC™) or non-CAD/CAM process (Narval™) on OSA patient oropharyngeal airway volume (OV).

Methods and measurements

12 OSA patients were enrolled. Patients were then randomly assigned to use either the CAD/CAM appliance or the non-CAD/CAM for one month. A repeat PG and CBCT with the device in mouth were performed at each follow-up. The second device fitting took place after a one week wash-out period.

Results

Population: mean age: 53±9 y, BMI: 27±4 kg/m², 8 men (73%), mean AHI: 22±7.8 (evt/h), mean ODI: 19±6, mean ESS: 6.7±4.8, mean occlusal vertical dimension (OVD): 64±5 mm, mean OV: 20 007±4442 mm3.

Upper airway volume increased significantly with the CAD/CAM device (7725±6540 mm3, p=0.008) but not with the non-CAD/CAM device (3805±7806 mm3, p=0.13). AHI with CAD/CAM & non-CAD/CAM decreased respectively to 9.4±6.3 evt/h (p=0.003) & 14.7±11.7 evt/h (p=0.083). ODI with CAD/CAM and non-CAD/CAM decreased respectively to 11.9±6.8 (p=0.011) and 15.5±19.2 (p=0.074). The vertical dimension of occlusion increased significantly following treatment with both MRD devices (both p=0.003), but was significantly less pronounced with the CAD/CAM device (mean difference: -2.7±1.7 mm, p=0.003). ESS improved significantly with both MRD. Mandibular advancement at FU (MA) was the same or both MRD 6.4±1.2 mm (CAD/CAM) vs 6.3±1.3mm (non-CAD/CAM) p=0.317.

Conclusion

The CAD/CAM (Narval CC™) appliance was associated with a significant increase in upper airway volume that may be caused by a less pronounced vertical separation between the jaws when compared to the non-CAD/CAM design.

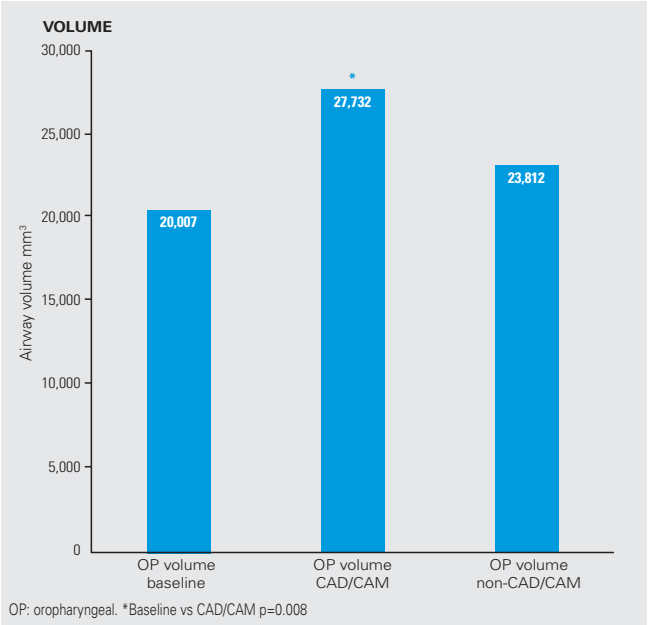


Fig. 1: CAD/CAM Narval appliance provides more upper airway volume increase than non-CAD/CAM.

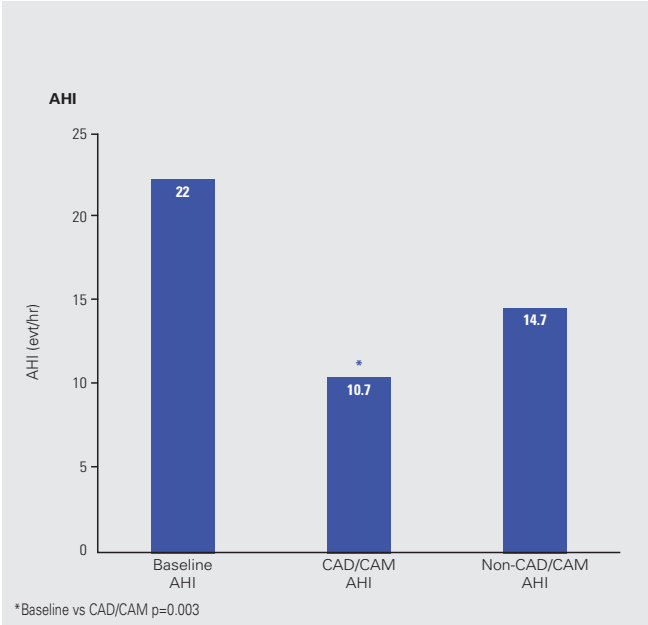


Fig. 2: AHI with CAD/CAM & non-CAD/CAM appliances decreased respectively to 11±6.3 evt/h (p=0.005) & 14.7±12 evt/h (p=0.083).

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

2 Attali V et 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* 2019 (in press).

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

4 Cheze L and Navailles B, Impact on temporomandibular joint of two mandibular advancement device designs, *ITBM-RBM* 2006.

5 Kerbrat A et al, Clinical Impact of 2 types of Mandibular Retention Devices (MRD) - Narval CAD/CAM vs Narval non-CAD/CAM – on OSA: ESTAMPS STUDY, *European Respiratory Journal* 2018.

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. *Sleep Medicine* 2015;11(7):773-793.

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