ResMed

Narval CC™

The Orcades Study, 5-year follow-up[1]

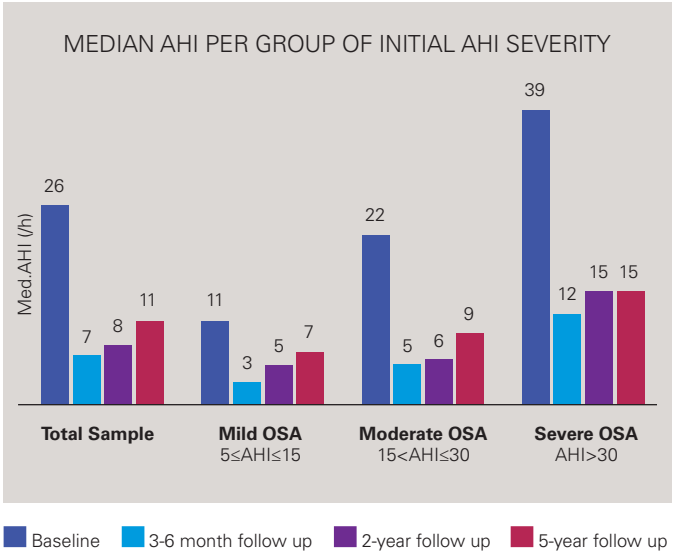
Orcades

ORCADES, supported by ResMed, is the **largest prospective multicentre study ever undertaken on mild to severe apnoea patients treated with a Mandibular Repositioning Device (MRD)**. 331 patients treated with a CAD/CAM Narval appliance were followed over 5 years. The study was designed to provide clinical evidence of the benefits of the Narval appliance in the treatment of Obstructive Sleep Apnoea (OSA) in current practice.

Efficacy on AHI

- After 5 years, the median **Apnoea–Hypopnoea Index (AHI) was divided by two** compared to baseline (from 26 to 11).
- At 5-year follow up, **the success rate* averaged 52%** across all three patient groups (mild, moderate and severe OSA).
- **Efficacy on AHI was particularly good in the severe OSA group,** where the success rate reached 62% and median AHI remained at 15, even after 5 years.

Overall, the slight increase in AHI at 5 years compared to the 3-6-month follow up results was not associated with symptom worsening. This confirms the importance of **regular objective monitoring of OSA to ensure that AHI is well controlled.**



*Success rate: % of patients with an initial AHI reduction ≥50%

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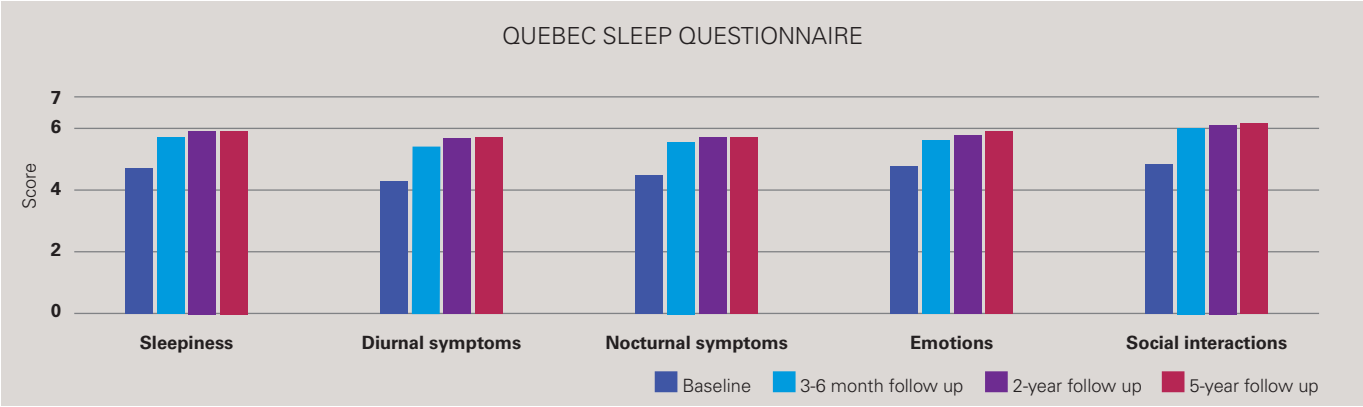
Quality of life

- **Patients significantly improved their quality of life over time**
  Each domain score of the Quebec Sleep Questionnaire improved after 3 months of treatment. Improvement was maintained at 5-year follow-up.



- **Patient sleepiness significantly improved at 3 months and remained low over the long term**
  Average Epworth scores decreased from 11.2 at baseline to 7.7 at 3 months ($p<0.0001$) and remained significantly improved at the last 5-year visit (7.3, $p<0.0001$).

Therapy withdrawals due to side effects

- **Only 9.4% of patients withdrew from therapy due to clinical side effects.**
- No patients withdrew from the therapy due to tooth migration or dental mobility.

SIDE EFFECTS	n**	% vs total sample
Dental pain	8	2.4
TMJ disorders	7	2.1
Gingival pain or gingivitis	5	1.5
Mouth pain or irritation	2	0.6
Occlusion change	2	0.6
Suspected allergy	2	0.6
Dental fracture or prosthesis loosening	2	0.6
Mouth dryness or hyper salivation	1	0.3
Discomfort	1	0.3
Nausea or vomiting	1	0.3
Tooth migration or dental mobility	0	0
TOTAL	31	9.4

Compliance

The long-term efficacy and tolerability of Narval CC explains the high level of daily usage* after 5 years**

- Mean compliance remained high at 6.7 hours per night, 6.5 days per week.
- 90% of patients used the Narval CC MRD at least 7 hours per night.
- 83% of patients sleep with their Narval device every night.

** n=patients
*** As declared by patients

1. Internal data. ORCADES Statistical Report 5-year follow-up - ResMed id C274982

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