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Title: ORCADES: A prospective cohort study of severe obstructive sleep apnoea (OSA) patients receiving second line-treatment with a mandibular repositioning device (MRD)

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Body: Background: MRDs are an alternative therapy for OSA especially in pts not treated with continuous positive airway pressure (CPAP). Aim: ORCADES is a French prospective multicentre observational cohort study providing long-term data (5 years) on 360 OSA pts who refused or did not tolerate CPAP and were treated with a MRD. Results for the first pts treated are shown. Methods: OSA pts were screened by sleep physicians and referred to a dental specialist who fitted a custom MRD (CadCam; Narval) in eligible pts and did mandibular advancement (MA) titration. Objective sleep data, symptoms, sleep quality, side effects and compliance were evaluated. Treatment success was defined as a $\geq 50\%$ decrease in apnoea-hypopnoea index (AHI) from baseline. Results: 232 pts had been treated by 31 Jan 2013 (71% male, age 53.2 ± 11.9 y, 49.8% previously treated with CPAP, mean AHI $29 \pm 15/h$). AHI was 5-15/h (14%) and 15-30/h (44%) with severe sleepiness or $>30/h$ (42%), 79% of pts were daily snorers and 42% had severe snoring. Final mean MA was 7.3 ± 2.2 mm (75% maximum MA). To date, 143 pts have had a 3-month assessment. Treatment success rate was 84%, regardless of OSA severity or previous CPAP. AHI was $<10/h$ in 85% ($-12.6 \pm 7.7/h$) and 39% ($-26.0 \pm 12.5/h$) of pts with baseline AHI 5-30/h or $>30/h$, respectively. Frequency and duration of

snoring were reduced by 50% (sleep data) and sleep quality improved. Only 10 pts (4%) stopped treatment early for side effects. Compliance was excellent (6.7 h/night, 6.6 days/wk). Conclusions: CadCam custom MRD is an effective therapy for moderate-to-severe OSA that can be used for pts refusing or noncompliant with CPAP.