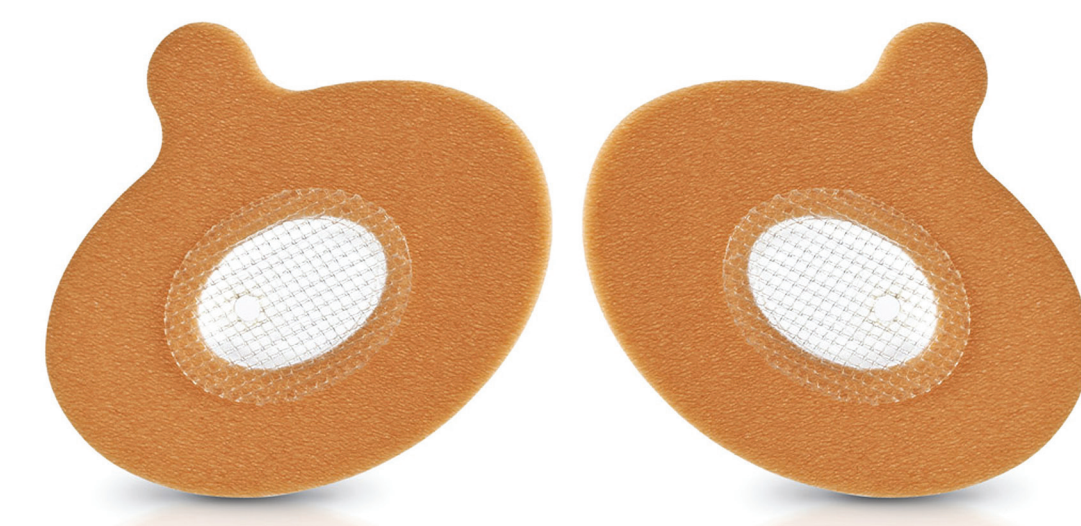


# An Analysis of Responders to Nasal Expiratory Positive Airway Pressure (EPAP) During Long-term Follow-up

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## Introduction

A nasal expiratory positive airway pressure (EPAP) device (Provent Therapy, Ventus Medical) is a safe and effective treatment option for patients with obstructive sleep apnea (OSA). A previously published 12-month long term use study compared outcome measures at week 1 and month 12 in patients who had a positive clinical response to EPAP at the conclusion of a 3 month long sham-controlled randomized study. The analysis below provides additional data showing the progression of outcomes at intermediate time points between week 1 and month 12.

## Methods

Patients in the EPAP arm of the randomized study who met adherence and efficacy criteria at month 3 were enrolled in the 12 month follow-up study. Device-on and device-off polysomnograms (PSG) were completed at week 1 and month 3, and a device-on PSG was completed at month 12. Subjective sleepiness was evaluated with the Epworth Sleepiness Scale (ESS) at baseline, and months 3, 6, 9, and 12.

## Results

There were 41 patients enrolled in the 12-month follow-up study; 31 had an AHI > 5 at baseline. In these 31 subjects, median AHI was reduced from 17.5 (device-off) to 5.0 (device-on) at week 1, 18.1 (device-off) to 5.2 (device-on) at month 3, and 17.5 (device-off at week 1) to 5.0 (device-on) at month 12. Similarly, the median oxygen desaturation index (ODI) was reduced from 13.7 to 6.1 at week 1, from 11.1 to 5.5 at month 3 and from 13.7 to 8.6 at month 12. The mean ESS at baseline was 10.6 compared to 7.4 at month 3, 6.6 at month 6, 6.2 at month 9 and 5.8 at month 12 ( $p < 0.01$  at each time point compared to baseline).

## Conclusion

Nasal EPAP reduced the AHI and ODI, and progressively improved daytime sleepiness at multiple time points throughout a 12 month follow-up period.

Figure 1. Median AHI Over Follow-up (n=31)

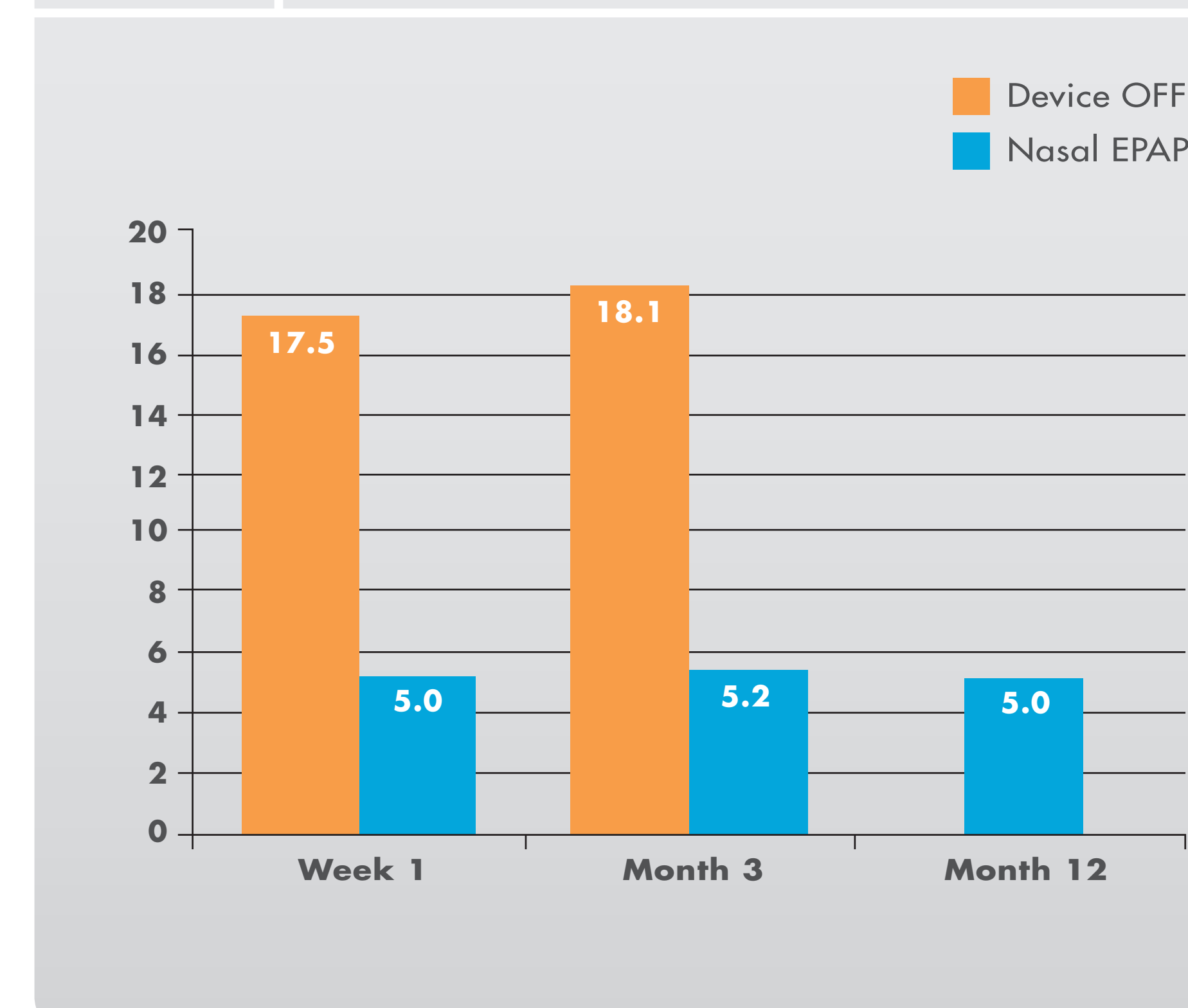


Figure 2. Average ESS (n=31)

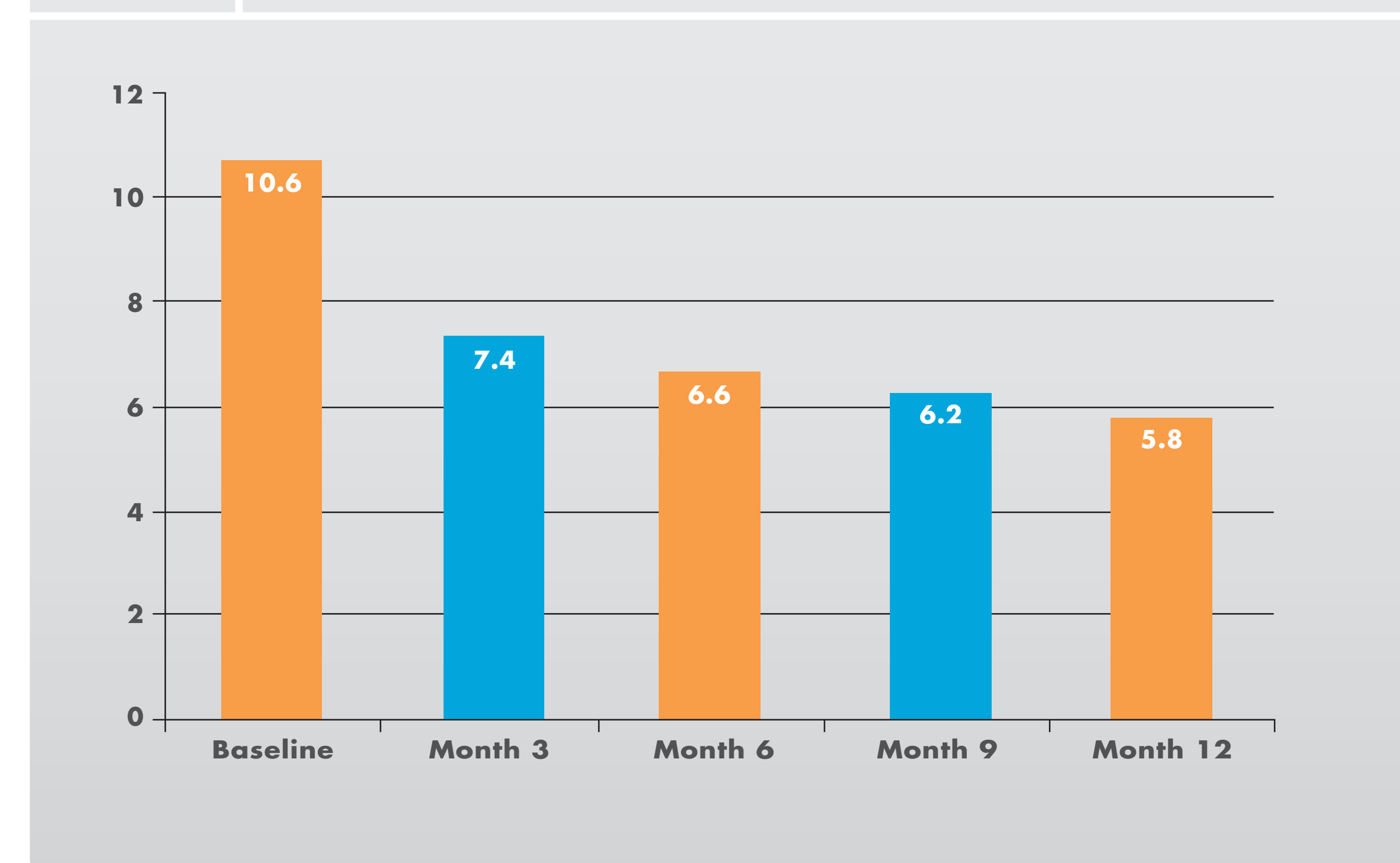


Figure 3. Median %TST <90%SaO2 Over Follow-up (n=31)

