# Continuous Open Airway Therapy (COAT) for Obstructive Sleep Apnea (OSA): Adherence linked to Subjective Perceptions of Device or Treatment Comfort Equals Compliance

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**Purpose:** The objective of the study was to investigate the experience of patients using continuous open airway therapy with a custom oral device for the treatment of OSA.

**Method:** A questionnaire-based survey was conducted via email to 1493 patients who has been prescribed a SomnoDent oral device for the treatment of obstructive sleep apnea.

**Results:** There were 246 respondents (total response rate 16.4%). 97.56% of respondents stated they were still using their oral device since being fitted. The period of treatment range from 1 to 22 months. 93% of respondents reported that they wear their oral device all night. When asked about the comfort, the results were as follows; 21.95% - Excellent, 35.77% - Very good, 33.98% - Good, 4.47% - Not good, 2.43% - Dissapointing. Only 1 patient stated the device could not be worn due to comfort.

**Conclusions:** A high level of adherence and comfort with treatment was reported using a custom device for continuous open airway therapy across all levels of severity of obstructive sleep apnea. A significant number of patients had previously used CPAP.

**Introduction:**

Obstructive sleep apnea is a common disorder. Recent estimates of the prevalence of obstructive sleep apnea estimate that I in 5 adults have at least mild sleep apnea and 1 in 15 has at least moderate sleep apnea[1].

Although CPAP is an effective treatment option when adherence is defined at greater than 4 hours of nightly use, the estimates of non-adherence to therapy range between 46-83%[2]. Continuous open airway therapy has been reported to have a better adherence. 76% of patients reported using their device after one year and 62% after 4 years[3]. In patients who continue to use their device after 5 years the self reported adherence is good with over 90% reported usage rates of over 4 nights per week for more than half the night[4].

The adherence to therapy has important implications. Health outcomes of CPAP and COAT were similar in a recent study by Phillips et al. since the greater efficacy of CPAP may be offset by the greater adherence to COAT[5].

Our study assesses the adherence rates observed in our patient population using the SomnoDent Custom device as well as analyzed factors that may contribute or influence continuous open airway therapy use.

## Materials and Methods

The sample comprised of 246 respondents to a questionnaire based survey that was administered via email. A total of 1493 surveys were sent out with a 16.4 percent response rate. All patients had been prescribed a SomnoDent device.

*When was your SomnoDent device fitted?*
*Are you still wearing your device?*
*Did you have a sleep study prior to treatment?*
*If yes, what was your OSA diagnosis?*
*Have you had a sleep study following having your SomnoDent fitted?*
*If yes, what was your OSA diagnosis?*
*Did you ever use CPAP prior to your SomnoDent?*
*How long do you wear your SomnoDent device during the night?*
*How would you describe the comfort of your SomnoDent device?*
*How would you describe your sleeping experience since having your SomnoDent fitted?*

Questionnaire sample (text box)

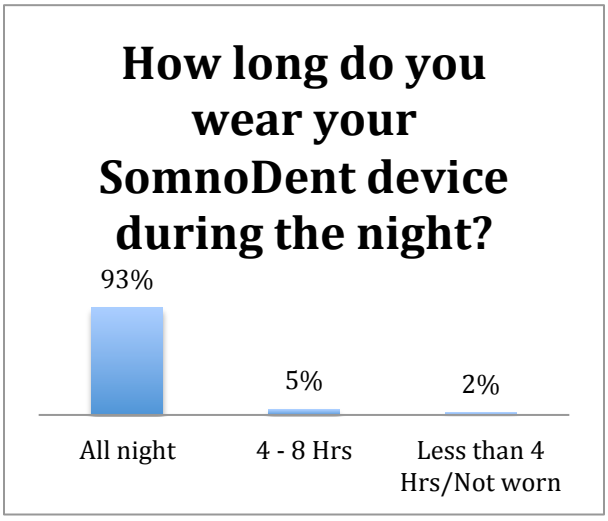
## Results

Amongst the 246 respondents, 56.1% had previously used CPAP to treat their obstructive sleep apnea. A baseline sleep study had been performed on 91.06% of the respondents with 21.96 % having mild OSA, 36.56% having moderate OSA and 19.52% having severe OSA. 21.96% did not disclose the severity of OSA at diagnosis.
97.56% of patients stated they were still using their device since being fitted.
When asked about the comfort of COAT the results were 21.95% excellent, 35.77% very good, 33.98% Good, 4.47% Not good 2.43% disappointing.
When asked about their sleeping experience since having COAT fitted responses were 15.45% - Excellent, 36.59% - Very Good, 39.43% - Good, 4.06% - Not Good, 4.47% - Disappointing. The average time that the patient had used the COAT device prior to the survey was 4.4 months. The range was 1 month to 22 months.

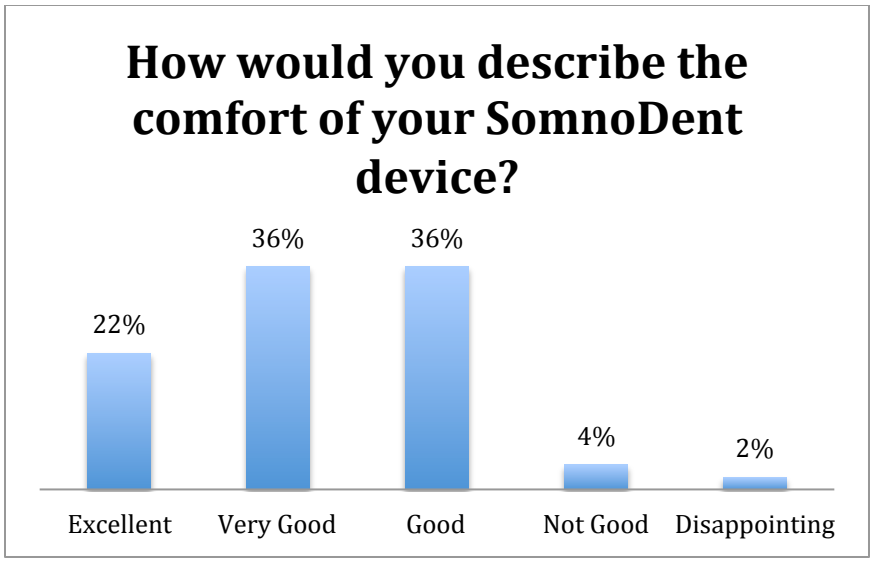
## Discussion:

In our sample there was a range of severity of obstructive sleep apnea noted. This is an expected result given the current American Academy of Sleep Medicine guidelines for treatment, which recommends COAT for mild to moderate OSA based on patient preference and recommends COAT for severe OSA in patients who refuse or fail CPAP treatment[6]. 51% of patient had previously tried CPAP. Although we did not ask the specific question there is increasing literature showing that short-term treatment with COAT for patients on CPAP may be reasonable[7]. 17.41 % of patients were unaware of the severity of their OSA despite having had a study to confirm the diagnosis. This is likely because not all patients have a copy of their results or may not have had an in depth review of results or may not accurately recall discussion of the results with their physicians.

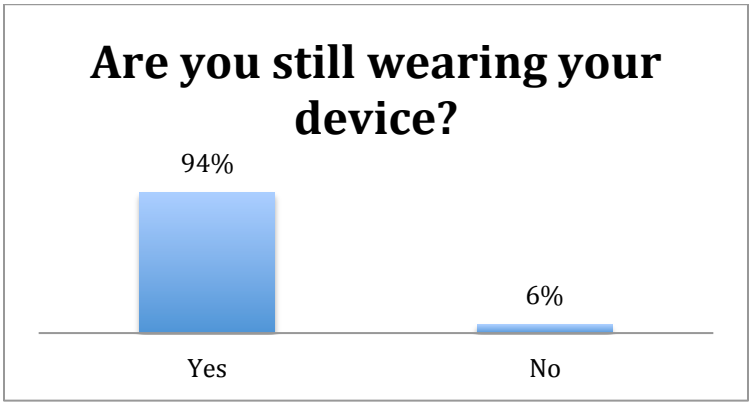
A significant percentage of patients had not yet had follow up studies. The average time between delivery of the COAT device and the study questionnaire was 4.4 months. We expect a significant number of patients would subsequently follow up to have a formal assessment as recommended by the current guidelines. The efficacy of COAT has been extensively studied however. With success defined as a post-treatment AHI < 10 events/h, success rates for COAT are in the range of 30% to 85% versus 62% to 100% for CPAP[8]. High treatment adherence may lead to overall lower cost of care for the OSA patient.




The adherence rates of 97.56 percent are likely related by the custom fit and comfort of the device. Direct comparison of the efficacy of thermoplastic non-custom and customized mandibular advancement devices in a crossover study of 35 patients over 4 months of each device found post-treatment AHI was reduced only with the custom-made device. The thermoplastic device also showed a much lower rate of treatment success (60% vs. 31%). Lower adherence to the boil and bite device was attributed to poorer retention. High adherence of SomnoDent may be due to the SMH BFlex liner. Device comfort is due to the quality of materials and quality of manufacturing. High nightly usage rate could be due to the simplicity of COAT where patients do not need to remove the device if they wake up and leave the bed for a short time. The majority of patients (82%) preferred the customized device at the end of the study[9].




Although the remarkable adherence rates in this study are encouraging, the results are limited by the subjective nature of the questionnaire. Objective adherence data with COAT is however reassuring. A recent study showed high agreement between objective and subjective compliance data at 1-year. Follow-up was reported showing a mean subjective overestimation of 30 min. The discontinuation rate for COAT at 1-year follow-up was 9.8%. The objective mean use rate was 6.4 ± 1.7 h/night at 1-year follow-up in continuing users, with a regular use rate of 83%[10]. Higher nightly usage rate could be due to the simplicity of COAT where patients do not need to remove the oral device if they need to get up during the night.




Future studies should include objective measurements of compliance. With the introduction of the embedded micro recorder technology we anticipate this to become an integral part of clinical practice for treating OSA with COAT.

References

1. *Young T, Peppard PE, Gottlieb DJ. Epidemiology of Obstructive Sleep apnea: A population health perspective. Am J Respir Crit Care Med. 2002 May*

*1;165(9):1217-39*

2. *Weaver TE, Grunstein RR. Adherence to continuous positive airway pressure therapy: the challenge to effective treatment. Proc Am Thorac Soc. 2008 Feb 15;5(2):173-8. doi: 10.1513/pats.200708-119MG*
3. *Walker-Engström ML, Wilhelmsson B, Tegelberg A, Dimenäs E, Ringqvist I. Quality of life assessment of treatment with dental appliance or UPPP in patients with mild to moderate obstructive sleep apnoea. A prospective randomized 1-year follow-up study. J Sleep Res. 2000 Sep;9(3):303-8.*
4. *de Almeida FR1, Lowe AA, Tsuiki S, Otsuka R, Wong M, Fastlicht S, Ryan F. Long-term compliance and side effects of oral appliances used for the treatment of snoring and obstructive sleep apnea syndrome. J Clin Sleep Med. 2005 Apr 15;1(2):143-52.*
5. *Phillips CL, Grunstein RR, Darendeliler MA, Mihailidou AS, Srinivasan VK, Yee BJ, Marks GB, Cistulli PA. Health outcomes of continuous positive airway pressure versus oral appliance treatment for obstructive sleep apnea: a randomized controlled trial. Am J Respir Crit Care Med. 2013 Apr 15;187(8):879-87 doi: 10.1164/rccm.201212-2223OC*
6. *AASM guidelines for Oral Appliance Therapy*
7. *Almeida FR1, Mulgrew A, Ayas N, Tsuda H, Lowe AA, Fox N, Harrison S, Fleetham JA. Mandibular advancement as a short-term alternative treatment in patients with obstructive sleep apnea already effectively treated with continuous positive airway pressure. J Clin Sleep Med. 2013 Apr 15;9(4):319-24. doi: 10.5664/jcsm.2576.*
8. *Sutherland K, Vanderveken OM, Tsuda H, Marklund M, Gagnadoux F, Kushida CA, Cistulli PA. Oral Appliance treatment for obstructive sleep apnea: an update. J Clin Sleep Med. 2014 Feb 15;10(2):215-27. doi: 10.5664/jcsm.3460.*
9. *Vanderveken OM, Devolder A, Marklund M, Boudewyns AN, Braem MJ, Okkerse W, Verbraecken JA, Franklin KA, De Backer WA, Van de Heyning PH. Comparison of a custom-made and a thermoplastic oral appliance for the treatment of mild sleep apnea. Am J Respir Crit Care Med. 2008 Jul 15;178(2):197-202. Epub 2007 Aug 2.*
10. *Dieltjens M, Braem MJ, Vroegop AV, Wouters K, Verbraecken JA, De Backer WA, Van de Heyning PH, Vanderveken OM. Objectively measured vs self-reported compliance during oral appliance therapy for sleep-disordered breathing. Chest. 2013 Nov;144(5):1495-502. doi: 10.1378/chest.13-0613.*