BMJ Open Respiratory Research

# Patient compliance and satisfaction with a new forehead device for positional obstructive sleep apnoea treatment: a post hoc analysis of a randomised controlled trial

Laura Hidalgo-Armas,[1,2] Sandra Inglés,[1] Rafaela Vaca,[3,4] José Cordero-Guevara,[5] Joaquín Durán-Carro,[1] Jorge Ullate ,[1] Jordi Rigau,[6,7] Joaquin Durán-Cantolla,[8,9] On behalf of the Spanish Sleep Network

**To cite:** Hidalgo-Armas L, Inglés S, Vaca R, *et al*. Patient compliance and satisfaction with a new forehead device for positional obstructive sleep apnoea treatment: a post hoc analysis of a randomised controlled trial. *BMJ Open Respir Res* 2023;**10**:e001503. doi:10.1136/bmjresp-2022-001503

Received 13 October 2022
Accepted 6 June 2023



For numbered affiliations see end of article.

**Correspondence to**
Laura Hidalgo-Armas;
lauhidalgo92@gmail.com

## ABSTRACT

**Background** The influence of body position in obstructive sleep apnoea patients is well known. A positional therapy device placed at the forehead has proven to be effective in reducing the severity of positional obstructive sleep apnoea (POSA) symptoms. The aim of the study was to evaluate patients' therapy compliance and satisfaction in the short term and mid-term.

**Methods** A post hoc analysis of a randomised controlled trial was conducted using an inactive device (ID) or an active device (AD) for 3 months. The primary outcomes were device usage and the percentage of patients with good compliance (defined as device use for more than 4 hours per night and more than 70% of nights per week). Secondary outcomes included time spent with head in the supine position, patient satisfaction and side effects.

**Results** The median duration of using the device was 6.9 hours in the ID group and 6.7 hours in the AD group (p=0.309), and the durations were similar throughout the follow-up period and from the first day of use. The percentage of patients with good compliance was similar and greater than 60% in both groups. The median time spent with head in the supine position was significantly lower in the AD group (2.9%) than in the ID group (12.4%) since the first day of treatment. Both groups showed satisfaction scores values above 8.5 (out of 10) in all items, while side effects were scarcely reported.

**Conclusion** High device compliance was achieved in POSA patients, both in terms of device usage time and percentage of days used. Patients were highly satisfied, and the device effectively reduced the time spent with the head in the supine position from the first day of use.

### WHAT IS ALREADY KNOWN ABOUT THIS TOPIC

⇒ The high prevalence of obstructive sleep apnoea (OSA) and the presence of a postural component in 60% of patients make research in this field a priority. However, there is currently no consensus on the management of positional OSA (POSA) patients. Moreover, standard treatment with continuous positive airway pressure (CPAP) has shown low long-term compliance rates.

### WHAT THIS STUDY ADDS

⇒ In this randomised controlled trial, the use of a new positional therapy device placed at the forehead in POSA patients provided high compliance rates, with values above the usual ones for CPAP treatment. The effect of the device was immediate from the first day and was sustained over time, avoiding the need for a training period. Patients were highly satisfied with the device, and minor side effects were reported.

### HOW MIGHT THIS STUDY AFFECT RESEARCH, PRACTICE OR POLICY

⇒ This study provides additional data on the use of this vibration-based forehead device that could be useful in the clinical management of POSA patients. The typical use of an adaptation period when initiating positional treatment is questioned. This treatment modality could be used as a primary therapy in POSA patients or as an alternative in patients who cannot tolerate or are not compliant with the standard CPAP treatment.

## INTRODUCTION

Obstructive sleep apnoea (OSA) is defined as a chronic multifactorial disease.[1] It is characterised by recurrent complete or partial collapse of the upper airway during sleep[2] and is a recognised risk factor for complications (cardio- and cerebrovascular diseases), poor quality of life or workplace and road accidents.[3 4]

Concerns have increased about an effective treatment, since the effects of untreated OSA are well described.[4] Hygiene and dietary measures should be implemented in all patients with OSA, regardless of whether continuous positive airway pressure (CPAP)

therapy is indicated. CPAP is an effective treatment to reduce OSA severity and remains the treatment of choice in OSA patients.[5]

However, the American Academy of Sleep Medicine also assumes that a significant proportion of patients are unable to tolerate CPAP therapy.[6] In addition, the efficacy is limited by poor adherence or compliance and by side effects such as discomfort, airway dryness, skin irritation, claustrophobia, etc.[4] Generally, the prevalence of non-compliant CPAP users is approximately 40%–50% in the long term.[3 6 7]

Despite these shortcomings, CPAP continues to stand as the first-line treatment for OSA.[6] However, there is a growing interest in non-CPAP alternatives for patients diagnosed with mild or moderate OSA or for those who refuse conventional treatment.[8] The influence of body position in OSA is well recognised, with the symptom severity being increased when patients are in the supine position.[9–12] This effect is due to a posterior displacement of the tongue, favoured by gravity, which increases upper airway collapsibility,[9] Moreover, decreased lung volume occurs in the supine position due to diaphragm displacement.[9]

The prevalence of positional OSA (POSA) varies approximately 50%–60%.[9 13] POSA is defined as an Apnoea-Hypopnoea Index (AHI)≥5 events/hour and at least twice as high in the supine position as in other positions.[1 10] Recently, interest in POSA has increased since a large percentage of patients may show significant improvements by simply changing their position during sleep.[1] An increasing amount of literature is being published on the role of positional therapy (PT), including suggestions of strategies to prevent sleeping in the supine position.[1 14]

Some of these strategies are based on passive physical means, such as a bulky mass strapped to the patient's back,[12] special pillows[12] or the tennis ball technique,[12 15] which have been reported to be effective in reducing AHI.[12 15] However, due to backache, shoulder pain, discomfort or no improvement in sleep quality or daytime sleepiness, there is poor compliance, and subsequently, disappointing long-term results for passive PT, with compliance rates between 10% and 40%.[16 17]

For this reason, new active devices (AD) for PT, whose action mechanism is based on vibratory stimuli,[7] have been introduced into the therapeutic options for POSA management.[15 18] The studies suggest that this therapy successfully prevents POSA patients from adopting the supine position and consequently reduces the AHI without negatively influencing sleep architecture and with better acceptance in the short and long term.[19 20] In line with this trend, we developed a new forehead vibration-based device that has proven effective in the management of POSA patients.[3 21]

The main aim of this study was to evaluate the use and compliance of this forehead PT device in the short term and mid-term. The secondary aims were to analyse the effectiveness of the device in reducing time spent with the head in the supine position, to evaluate patient satisfaction and to identify possible side effects.

## METHODS

### Design and settings

This is a post hoc analysis of a previous multicentre, randomised, prospective, parallel controlled trial (RCT).[21] Data analysed in this study correspond to patients using the device in randomisation arms for the inactive device (ID group) and AD group.

### Outcomes

The main outcomes were device usage time in the short term and mid-term in both groups, as well as the percentage of patients with good compliance, which was defined as device use for more than 4 hours per night and more than 70% of nights per week.[5] Secondary outcomes were the percentage of time spent with the head in the supine position, patient satisfaction and possible side effects.

### Inclusion and exclusion criteria

As described elsewhere,[21] the included patients were men and women aged ≥18 years diagnosed with POSA with standard polysomnography (PSG) with a total sleep time (TST)≥180 min and ≥20% of TST in the supine position. Patients were excluded if they had major problems involving physical mobility (such as paralysis or relevant pain); had a body mass index (BMI)>40 kg; had other sleep disorders or mobility problems that prevented them from having postural changes in bed; had cognitive impairment; were professional drivers; were involved in the handling of dangerous machinery; were shift workers, pregnant women or patients with serious illnesses; were patients with cardiovascular or respiratory comorbidity; experienced excessive relevant daytime sleepiness defined by an Epworth Sleepiness Scale (ESS)>12 points; were being treated with psychotropic drugs; were taking central nervous system stimulants or antidepressants; were illegal drug users; or had an intake >80 g of ethanol per day. All participants provided written informed consent.

### Procedures

#### Randomisation

The randomisation method was described elsewhere.[21] Each patient was instructed individually about the assigned treatment, with emphasis on avoiding the supine position by their own strategies (without external stimuli of bed partner) for all groups. In groups ID and AD, the provided devices were identical in design, size, colour and registry capacity and were delivered with the same handling and care instructions. The only difference was that devices in the ID group were set in the placebo mode, in which the vibration was deactivated, and devices in the AD group were set in the therapy mode, which

allowed vibration to be applied when needed. Therefore, patients remained partially blinded to whether they were receiving an active or ID. Information about devices was blinded to the researchers, outcome assessors and sleep technicians who downloaded the data from devices.

### Follow-up

During the follow-up visits (at weeks 1, 4, 8 and 12), the following items were recorded: anthropometric variables, subjective satisfaction and possible side effects derived from the use of the treatment. Satisfaction with therapy was evaluated by asking patients to score different items through Likert scales (being 1 'very bad' and 10 'very good'), focusing the attention on the ease of use, comfort, device weight, device size and ease of transport. The questionnaire about side effects included the most frequently foreseen adverse events that could occur during device use, based on the experience of a previous pilot study: (3) 'discomfort' during device use; 'difficulty to sleep', defined as difficulty falling asleep or staying asleep at night; 'awakenings', defined as frequent conscious awakenings during the night; 'morning headache'; 'sweating' in the forehead due to the fastening adhesive and 'skin irritation', defined as skin soreness or inflammation in the area under or around the device placement. Moreover, a blank space was left with the item 'other' for patients to describe other adverse events, if any. In addition, at each follow-up visit, the data recorded by the device were downloaded with dedicated software (SomniLab, Sibelmed, Spain).

### Description of the somnibel device and recorded data

This new PT device (Somnibel, Sibelmed, Spain) is a lightweight (17 g) and small (52×32×14 mm) device that measures head position and generates a gentle vibrating stimulus based on the position of the head, regardless of trunk position.[21] The device is placed on the patient's forehead using a breathable fastening adhesive. The device begins vibrating when the patient lies in the supine position for more than 60 s and has four increasing intensities if the patient remains in the supine position for a longer time. The vibration stops when the patient changes from the supine to a non-supine position or after 20 min at maximum intensity. The devices that were provided to both groups (ID and AD) recorded each date and time that the device was used, the usage time (time elapsed between device OFF and ON) and continuous monitoring data of forehead position during each night throughout the follow-up period.

After downloading the recordings to the computer, SomniLab software provided summary data for each device use, such as usage time or percentage of total recording time in each forehead position. The SomniLab database was exported to CSV (Comma Separated Values) format, allowing us to evaluate the data on a day-by-day or on a weekly basis and to assess additional information such as the percentage of days used per week and the percentage of patients with good compliance, defined as device use for more than 4 hours per night and more than 70% of nights per week,[5] or with 'optimal' compliance, defined as device use for more than 5 hours per night and more than 70% of nights per week.[6]

### Statistical analysis

Data were analysed using SPSS V.16.0 (IBM). The results were expressed as the mean±SD or median (IQR) for continuous variables and the number of patients (percentage) for categorical variables. We used t-tests or Mann-Whitney U tests for comparison of quantitative variables and $\chi^2$ tests for categorical variables. Two-tailed p values less than 0.05 were considered significant. The CONSORT (CONsolidated Standards Of Reporting Trials) recommendations were followed. All data were analysed by the Araba University Hospital Research Unit. Statistical analyses were performed using a blinded evaluation of the group.

## Patient and public involvement

None

## RESULTS

The flow chart of the study is described in Hidalgo Armas *et al*,[21] showing a total of 87 patients included in the two arms evaluated in this study: 44 in the ID group and 43 in the AD group. Nine patients were lost to follow-up in these groups (6 patients in the ID group: 3 lost to follow-up, and 3 withdrew consent; and 3 patients in the AD group: 2 lost to follow-up and 1 withdrew consent), resulting in 78 patients completing the 12-week follow-up. The anthropometric characteristics and baseline PSG data are shown in table 1. Patients were middle-aged (52.2±11.6 years), mostly men (79.3%), without somnolence (ESS of 6.6±3.3) and overweight (BMI 28.6±4.0 kg/m$^2$). Both groups were comparable in all the evaluated parameters.

The median (IQR) global use of the device was 6.9 hours (5.8–7.6 hours) in the ID group and 6.7 hours (5.8–7.2) in the AD group (p=0.309) and similar in both groups throughout the 12 weeks (p>0.05, except in week 11 (p=0.048)) (figure 1A).

When analysing these compliance data daily, during the first fourteen days of therapy, the median use of the device was similar in both groups (p>0.05), with values higher than 6.5 hours (figure 1B).

Additionally, the percentage of patients fulfilling the criteria for good compliance was greater than 60% during the entire follow-up period in both groups (figure 2A), with a mean value of 72.0 (±45.4%) for the ID group and 85.0 (±36.6%) for the AD group (p=0.194). During the first 6 weeks, the percentage of compliant patients was higher in the AD group than in the ID group, although these differences were only significant in the second and third weeks. During the second part of the follow-up period, both groups had a similar percentage of compliant patients. When analysing the percentage of patients with 'optimal'

Table 1 Clinical and PSG characteristics in the ID and AD groups at baseline

| Clinical characteristics | ID (n=44) | AD (n=43) |
|---|---|---|
| Age (years) | 51.8±11.5 | 53.4±12.7 |
| Sex (men; %) | 35 (79.5) | 34 (79.1) |
| % patients with comorbidity* | 25 (56.8) | 27 (62.8) |
| % patients with hypertension | 20 (45.5) | 20 (46.5) |
| Systolic blood pressure (mm Hg) | 128.8±14.4 | 127.3±15.6 |
| Diastolic blood pressure (mm Hg) | 81.0±11.3 | 78.1±10.8 |
| Body mass Index (BMI) (kg/m$^2$) | 28.9±3.9 | 28.3±3.8 |
| Obesity (BMI>30 kg/m$^2$) | 11 (25.0) | 12 (27.9) |
| Neck circumference (cm) | 39.9±2.2 | 40.2±3.7 |
| Dermatological history | 6 (22.2) n=27 | 5 (16.1) n=31 |
| Epworth sleepiness scale | 7.5 (3.0–10.0) | 5.0 (4.0–8.0) |
| EuroQol (Thermometer) | 70.0 (60.0–81.5) | 80.0 (70.0–90.0) |
| Total sleep time (TST) (min) | 354.6±61.9 | 343.0±67.0 |
| Sleep efficiency (TST/registration in %) | 84.5 (75.9–88.3) | 80.2 (67.0–88.3) |
| % of TST in supine position | 45.6 (35.2–79.2) | 45.9 (32.9–72.1) |
| Arousals Index (events/hour) | 25.6 (15.9–39.9) | 21.9 (15.1–31.9) |
| % of TST in stage N1 | 7.9 (5.0–16.8) | 9.9 (6.3–14.5) |
| % of TST in stage N2 | 54.9±11.8 | 55.0±12.5 |
| % of TST in stage N3 | 16.5±10.4 | 16.2±8.9 |
| % of TST in REM sleep | 17.5±6.2 | 16.1±5.4 |
| % of Sleep N3+REM | 34.0±10.7 | 32.3±11.6 |
| Apnea-Hypopnea Index (AHI) | 30.5 (18.7–45.6) | 27.2 (17.6–35.1) |
| % patients with AHI mild (10–14.9) | 6 (13.6) | 6 (14.0) |
| % patients with AHI moderate (14.9–29.9) | 16 (36.4) | 19 (44.2) |
| % patients with AHI severe (>30) | 22 (50.0) | 18 (41.9) |
| AHI in supine position (events/hour) | 46.1 (33.8–69.2) | 48.4 (27.3–65.0) |
| AHI in non-supine position (events/hour) | 5.5 (0.7–14.1) | 6.9 (2.9–15.9) |
| Minimum SaO2 (mm Hg) | 83.0 (78.0–86.0) | 84.0 (81.0–87.0) |
| CT90 (% TST with SaO2<90%) | 2.4 (0.3–9.5) | 1.7 (0.1–6.3) |
| Desaturation index (events/hour) | 16.9 (11.6–33.2) | 19.5 (10.8–29.5) |
| Mean SaO2 (mm Hg) | 94.0 (92.0–95.0) | 94.0 (92.8–95.0) |

Data are expressed as the mean±SD, median (IQR) or number of patients (percent). There were no statistically significant differences between the two groups (p>0.05).
*Comorbidities included high blood pressure, obesity, diabetes, etc, but excluded important respiratory and heart diseases.
AD, active device; ID, inactive device; PSG, polysomnography; REM, rapid eye movement; SaO2, oxygen saturation.

compliance, we obtained values above 57% in the AD group throughout the whole follow-up period (figure 2B).

The median percentage of days per week using the device was similar between groups (p>0.05), with a median use of 91.4% (53.7%–99.7%) with ID and 89.4% (77.1%–96.8%) with AD (figure 3).

The median global percentage of time in the supine position recorded by the forehead device was 12.4% (8.2%–21.3%) in the ID group and 2.9% (1.3%–4.9%) in the AD group (p<0.001) and was significantly lower (p<0.001) in the AD group since the first week (figure 4A).

In addition, the median percentage of time in the supine position during the first 14 days was significantly lower in the AD group (p<0.001) than in the ID group, with values lower than 4% for the AD group and higher than 8% for the ID group. There were no remarkable changes during the first fourteen days of the study (figure 4B).

The results of the patient satisfaction survey at week 12 show mean values above 8.5 over 10 in all items evaluated, with low variability between patients and with no significant differences between the ID and AD groups (figure 5).

Questionnaires about side effects showed no significant differences between groups in terms of discomfort, difficulty sleeping, morning headache and sweating, with incidence rates of 35.9%, 10.4%, 12.5% and 10.0%, respectively, in the AD group. The percentage of patients reporting awakenings during the night in the AD group (60.6%) was higher than that in the ID group (29.7%) (p=0.006). Conversely, 27% of patients reported skin irritation in the ID group with no cases in the AD group (p=0.002) (table 2). No additional side effects were reported.

## DISCUSSION

This study provides additional clinically relevant information to the previous validation study of a forehead PT device.[21] The results show that the use hours, the percentage of nights used per week and the percentage of patients with good compliance were similar in both groups during the follow-up period. As expected, the percentage of time in the supine position was significantly lower in the AD group than in the ID group. No relevant side effects were reported, and patient satisfaction was high in both groups.

The median daily use of the device was higher than 6.5 hours/day in both groups, which is equivalent to other published studies with similar AD,[8 17 19 22–27] where the mean/median daily use ranged from 7.6 hours/night at a month[26] to 5.2 hours/night at 12 months.[20] The fact that daily use was almost equivalent between the ID and AD patient groups provides confirmation that the device vibration was well tolerated and did not hamper the routine use of the device. These results are in line with our previous publication in which no differences in arousal index or sleep efficiency were observed between both groups during PSG at the end of the follow-up period.[21]

As expected, our forehead device was able to significantly reduce the time patients spent with their heads in the supine position in the AD group. This is in agreement with our previous publication,[21] in which the AD group had a greater and significant reduction in the AHI and time in the supine position measured at the chest compared with the ID group, thus suggesting that

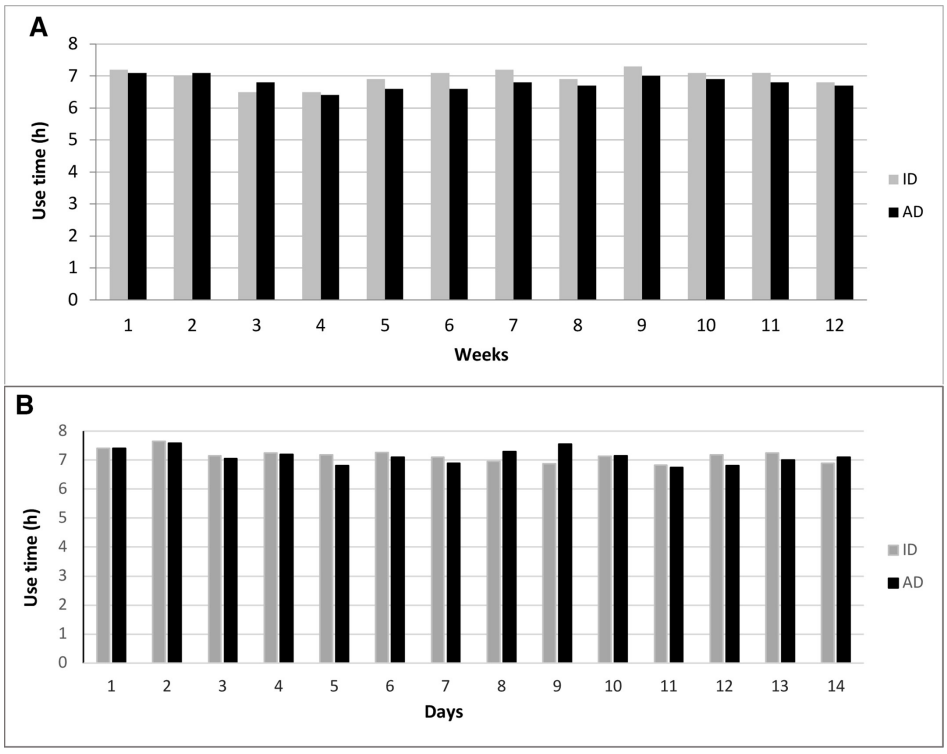


**Figure 1** (A) Median weekly device use during the follow-up period. (B) Median device use during the first 14 days of therapy. AD, active device; ID, inactive device.

applying the vibration at the forehead could be effective in changing both head and body position. Our results are not directly comparable to those of other studies, since all of them provide data on body position measured at the chest by PSG and not at the forehead. However, they reported similar reductions in the percentage of time in the supine position measured at the chest,[13 17 24 28–30] although many of them had values higher than our results.[1 9 19 20 23 25–27 31]

The time spent in the supine position measured by the device at the forehead in the ID group (median 12.4%) was low compared with the value measured at the chest by PSG in our previous publication (mean 43.7%).[21] Although not directly comparable, our findings are in line with the results of van Kesteren *et al*,[32] who reported an overall 23% reduction in mean time spent with their heads in the supine position compared with their trunks in the supine position, but their heads turned sideways. Additionally, this reduction increased to approximately 55% in those patients in whom head placement in the supine position aggravated the severity of OSA.[32] The reduction in time spent with patients' heads in the supine position compared with their trunks could be explained by a placebo effect, since the simple fact of placing the device on the forehead could induce the patients to modify their head position.

Likewise, it is necessary to highlight the role that head position plays in the reduction in the AHI, as has been shown in other studies[2 32 33] in which an overall reduction between −5 and −10 events/hour in the AHI is observed when only the head is in lateral position. This reduction can be of a greater magnitude in less obese patients,[2] such as POSA patients.[3] Consequently, applying the stimulus at the head can provide beneficial effects, allowing a greater freedom of movement for patients to adopt different positions during sleep (especially for women who sleep more in the supine position).[32 34] This could be very useful in the management of POSA patients who also suffer from musculoskeletal problems, especially shoulder and back pain, which has been reported as an adverse effect in other studies.[17 28]

Other devices that apply a vibration stimulus on the chest are designed to allow a training phase of 10 nights, in which the vibration activity increases progressively to gradually train the patient in avoiding the supine sleep position[19 26 28]; however, no data on the effect during the first nights have been previously reported. Our day-by-day analysis of the use time during the first 2 weeks of treatment revealed that patients in both the ID and AD groups used the device during the same time from the first day and that the use time was maintained relatively constant during the first 2 weeks and throughout the follow-up period. A similar behaviour was observed when analysing the percentage of time in the supine position on a daily basis; a reduced percentage of supine sleep in the AD group was also achieved from the beginning and with small variations during the follow-up period. These findings suggest that the therapeutic effect is obtained from the first night and that no training period is necessary. The earlier effect of the device avoids having patients undertreated during some days and is important for achieving a prompt reduction of symptoms.

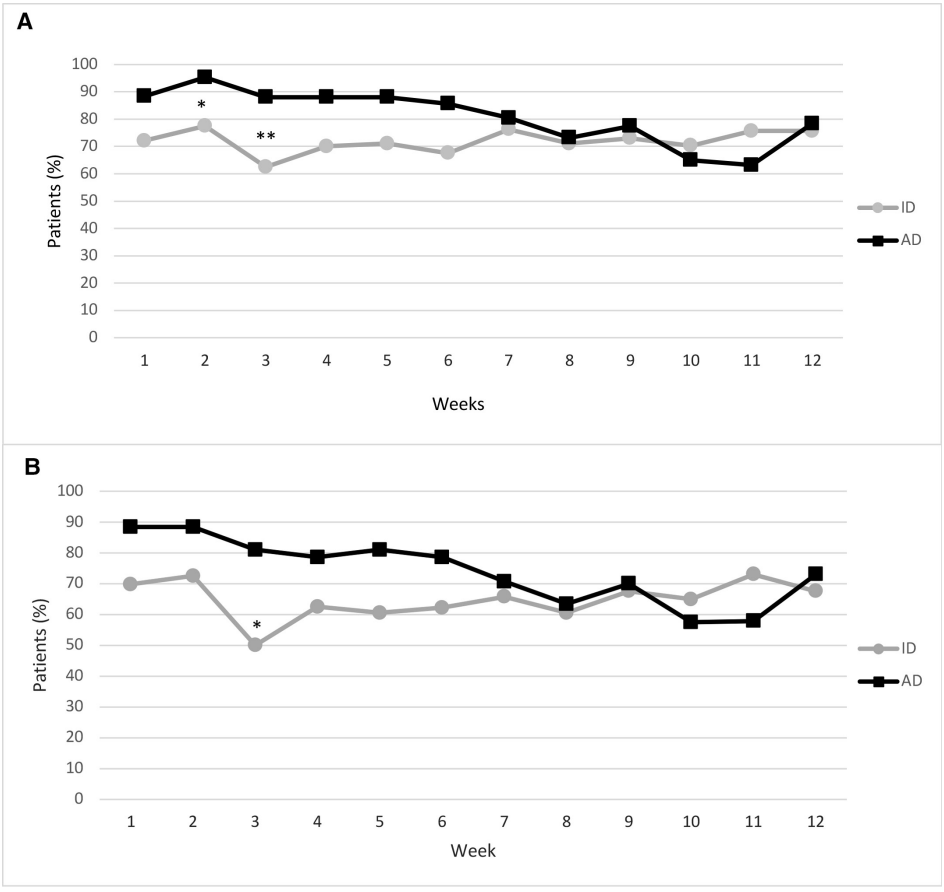


**Figure 2** (A) Percentage of patients with good compliance (>4 hours/day; >70% nights/week) during the follow-up period. *p=0.023; **p=0.01. (B) Percentage of patients with 'optimal' compliance (>5 hours/day; >70% nights/week) during the follow-up period. *p=0.005. AD, active device; ID, inactive device.

Patients in both groups used the device the same percentage of days per week during the whole follow-up period (85.7%), which is in agreement with other studies ranging between 100% at a month[13 17] and 69% at a year[8] and suggests that the treatment is well tolerated at mid-term.

In this study, we analysed two different criteria for compliance. First, good compliance was defined as ≥4 hours/night and ≥70% of nights as CPAP criteria.[5] We obtained high compliance rates in both groups, similar to other studies evaluated between 1 and 12 months of follow-up.[8 17 19 25 31] Considering that when this criterion

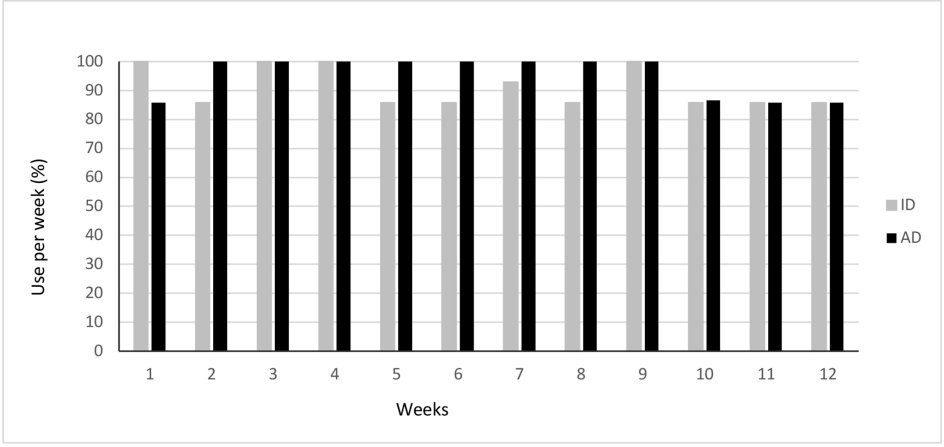


**Figure 3** Median weekly percentage of days using the device during the follow-up period. AD, active device; ID, inactive device.

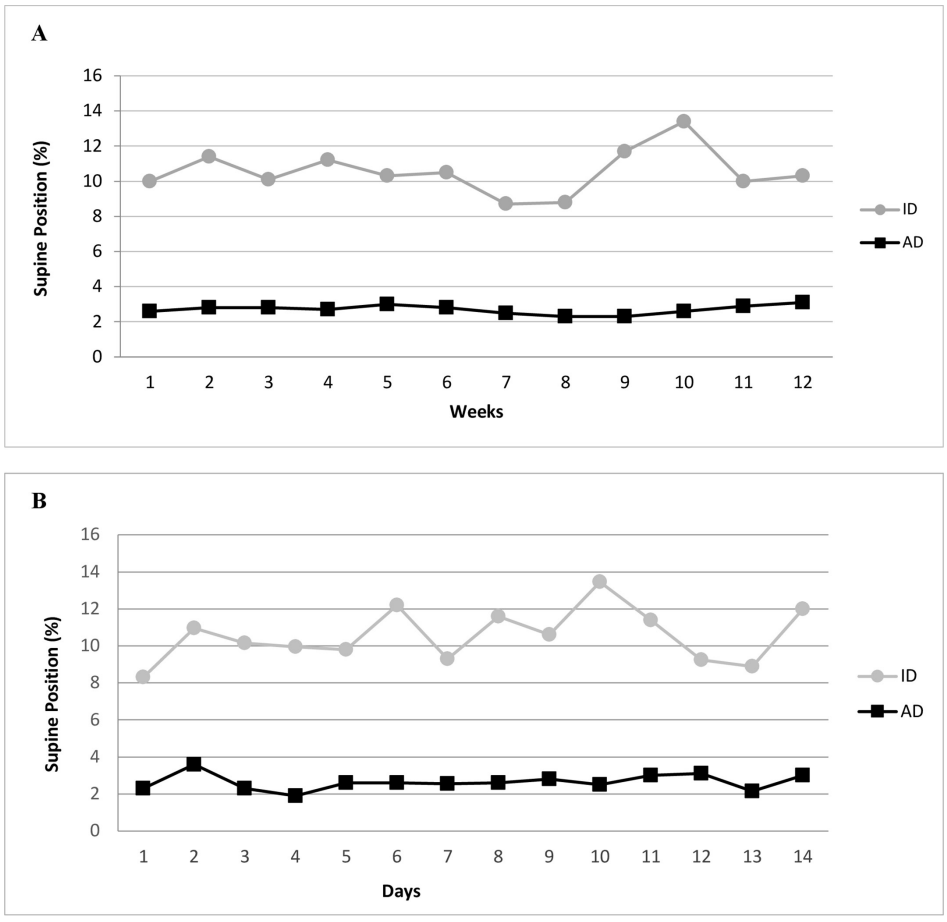


**Figure 4** (A) Median weekly percentage of time patients spent with their heads in the supine position during follow-up (p<0.001 for all weeks); (B) median percentage of time patients spent with their heads in the supine position during the first 14 days of therapy (p<0.001 for all days). AD, active device; ID, inactive device.

is applied to PT, it provides compliance rates higher than usual values for CPAP,[6] it can be speculated that a more restrictive criterion could be more suitable in positional treatment for encouraging patients to adhere to therapy. Additionally, it has been reported that the effectiveness of treatment is directly related to the amount of therapy used.[35 36] When considering 'optimal' compliance, we obtained compliance rates at 3 months with AD higher than values reported for CPAP at the same follow-up period.[36 37] Other studies on PT have also used this criterion, although with lower compliance rates.[24] This 'optimal' compliance criterion is in line with other studies that suggest that CPAP use of 5 hours/night is necessary to restore sleepiness to normal levels.[35 36]

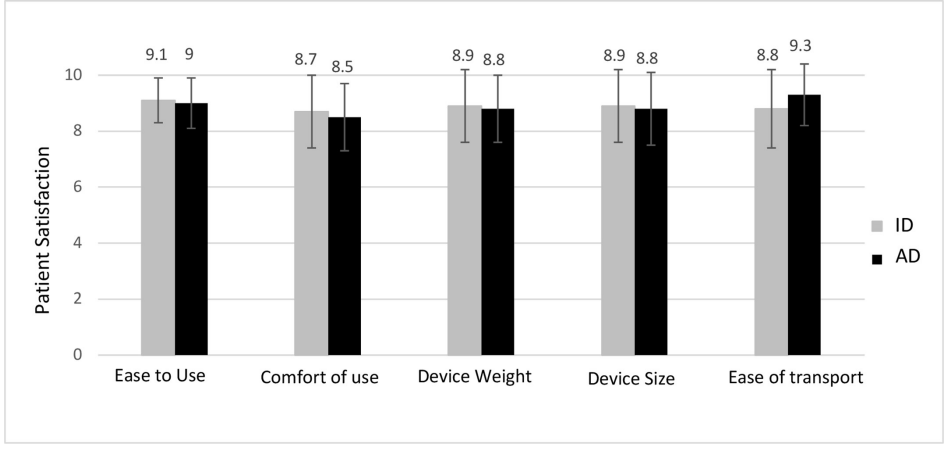


**Figure 5** Patient satisfaction at the end of follow-up period (12 weeks); all p values >0.05. AD, active device; ID, inactive device.

Table 2 Side effects reported by patients after using the device

| Item | Scale | Week 12 | |
|---|---|---|---|
| | | ID (%) | AD (%) |
| | | (n=37) | (n=39) |
| Discomfort | Never | 78.4 | 64.1 |
| | 1–4 t/month | 18.9 | 25.6 |
| | >2 t/week | 2.7 | 10.3 |
| | | (n=37) | (n=39) |
| Difficulty to sleep | Never | 89.2 | 89.6 |
| | 1–4 t/month | 8.1 | 5.2 |
| | > 2 t/week | 2.7 | 5.2 |
| | | (n=37) | (n=38) |
| Awakenings* | Never | 70.3 | 39.4 |
| | 1–4 t/month | 24.3 | 29.0 |
| | >2 t/week | 5.4 | 31.6 |
| | | (n=37) | (n=40) |
| Morning headache | Never | 83.8 | 87.5 |
| | 1–4 t/month | 13.5 | 10.0 |
| | >2 t/week | 2.7 | 2.5 |
| | | (n=37) | (n=40) |
| Sweating | Never | 81.1 | 90 |
| | 1–4 t/month | 16.2 | 7.5 |
| | >2 t/week | 2.7 | 2.5 |
| | | (n=37) | (n=40) |
| Skin irritation† | Never | 73 | 100 |
| | 1–4 t/month | 16.2 | 0 |
| | >2 t/week | 10.8 | 0 |

*p=0.006.
†p=0.002.
AD, inactive device; ID, inactive device.

Patients were satisfied with the device, rating all the studied items with values of 8.5 or higher over 10 in both groups. This positive evaluation is supported by the high daily use and the percentage of compliant patients compared with CPAP treatment.[8 9] Other studies have shown similar positive patient satisfaction.[25]

No major side effects that required interruption of treatment were recorded. Minor side effects were described, being the most reported in both groups; frequent awakenings were significantly higher in the AD group (60%), although half of them reported this side effect less than once per week. This value is in line with other studies on similar devices reporting awakening rates between 61% and 78%,[1 9] although higher than others.[20] This could be explained by the intended effect of the vibratory stimulus for inducing a body position change that might be subjectively perceived, as reported in other studies.[1 22 23 25] However, these awakenings did not translate into a worsening in subjective evaluation of device by patients (figure 5), in patient compliance (figure 4), or in objective measurements in macro and microstructure of sleep by PSG.[21]

Although a few patients reported skin irritation in the ID group, none of them required medical intervention, and all completed the study protocol. The differences between the two groups were attributed to chance.

Other side effects were reported occasionally. In other studies, side effects were also reported, such as discomfort, with rates between 17% and 29%,[1 20] difficulty initiating sleep in 67%,[1] or back or shoulder pain, with incidences ranging from 4% to 33%.[1 13 23 25] Since our device allows patients to turn only their heads without turning their bodies, it could be useful for those patients with musculoskeletal problems.

Our study had the limitation of not having a simultaneous recording of the postural device with the sleep study by PSG, which supposes the difficulty of comparing the changes in head position with respect to body. In addition, the lack of consensus regarding the criteria for measuring position changes and their influence on treatment results for PT assumes an additional difficulty when comparing different treatment modalities.

## CONCLUSION

This RCT showed that high compliance rates could be achieved with the use of the Somnibel device in patients with POSA, both in terms of use time and percentage of days used, with values above the usual compliance rates of CPAP treatment. The effect of the device is immediate from the first day and sustained over time, avoiding the need for an adaptation period. Patients were highly satisfied with the device use, and minor side effects were reported. These results reinforce the clinical utility of the device when considering the previously published data from this RCT in which a significant reduction in AHI, desaturation index and TST in the supine position was reported.[21] In addition, the device increased TST and the percentages of time spent in the N3 and N3+REM phases without disturbing the patients' sleep. This therapy could be very useful in the management of POSA regardless of its severity. Future studies are needed to evaluate its value when used in combination with other therapies or in other subgroups of POSA patients.

**Author affiliations**
[1]Sleep Disorders Research Group, Bioaraba Health Research Institute, Vitoria, Spain
[2]Alava Mental Health Network, Osakidetza Basque Health Service, Vitoria, Spain
[3]CIBER of Respiratory Diseases (CibeRes), ISCIII, Madrid, Spain
[4]Translational Research in Respiratory Medicine, IRB Lleida, Lleida, Spain
[5]Epidemiology and Public Health Research Group, Bioaraba Health Research Institute, Vitoria-Gasteiz, Spain
[6]Research, Development and Innovation Director, SIBEL S.A.U, Barcelona, Spain
[7]Biophysics and Bioengineering Unit, School of Medicine Barcelona, University of Barcelona, Barcelona, Spain
[8]Honorific Professor of the Medicine Department, UPV/EHU School of Medicine, Vitoria, Spain

[9]Director of the Eduardo Anitua Medical Clinic Sleep Unit, Eduardo Anitua Medical Clinic Sleep Unit, Vitoria, Spain

**Acknowledgements** The authors acknowledge the collaboration of the personnel in the Sleeps Units of the OSI Araba University Hospital and IRB Lleida. Additionally, the authors acknowledge Sibelmed, who lent the devices to perform the study

**Collaborators** The authors acknowledge the collaboration of the personnel in the Sleeps Units of the OSI Araba University Hospital and IRB Lleida. The Spanish Sleep Network: Carlos Egea, Jose L Manjón, Cecilia Tourino.

**Contributors** LH-A wrote the manuscript, collaborated in the recruitment of the patients and statistical treatment and participated and contributed to the review of the manuscript. JC-G contributed to the statistical treatment data. SI contributed to the coordination and control of patients and devices. JU and JD-Carro collaborated in data extraction from the devices. FB and RV contributed to the selection and recruitment of part of the sample. JD-C designed the study, reviewed the manuscript and contributed to all phases of the study. LH-A and JD-C were the guarantors of the research. All authors contributed to commenting on and editing the manuscript revisions. All authors read and approved the final manuscript.

**Funding** The Sibelmed Company provided the devices to perform the study but did not take part in the study design or management of the results. There was no economic contribution to the study by Sibelmed. This study was financed by the National Health Institute (ISCIII PI112/00243), the Health Department of the Basque Government (DSGV 2013) and the Spanish Respiratory Society (SEPAR 2014).

**Competing interests** LH-A received funding from SIBEL to present the data at an international conference. JR is an employee at SIBEL S.A.U.

**Patient and public involvement** Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

**Patient consent for publication** Not applicable.

**Ethics approval** This study involves human participants and was approved by Euskadi Ethics Committee (no 2014142), and registered in www.clinicaltrials.gov (NCT03336515).Participants gave informed consent to participate in the study before taking part.

**Provenance and peer review** Not commissioned; externally peer reviewed.

**Data availability statement** Data are available on reasonable request.



**ORCID iD**

Jorge Ullate http://orcid.org/0000-0003-1087-1232

## REFERENCES

1 De Corso E, Mastrapasqua RF, Fiorita A, *et al*. Efficacy and long-term follow-up of Positional therapy by Vibrotactile neck-based device in the management of Positional OSA. *J Clin Sleep Med* 2020;16:1711–9.
2 Zhu K, Bradley TD, Patel M, *et al*. Influence of head position on obstructive sleep apnea severity. *Sleep Breath* 2017;21:821–8.
3 Hidalgo Armas L, Turino C, Cordero-Guevara J, *et al*. A new postural device for the treatment of Positional obstructive sleep apnea. A pilot study. *Respir Med* 2019;151:111–7.
4 Cuesta F, Arboledas G, Grupo Español de Sueño (GES). Documento de Consenso Nacional Sobre El SAHS. *Arch Bronconumol* 2005;41:1–110.
5 Mediano O, González Mangado N, Montserrat JM, *et al*. International consensus document on obstructive sleep apnea. *Archivos de Bronconeumología* 2022;58:T52–68.
6 Rotenberg BW, Murariu D, Pang KP. Trends in CPAP adherence over twenty years of data collection: a flattened curve. *J Otolaryngol Head Neck Surg* 2016;45:43.
7 Barnes H, Edwards BA, Joosten SA, *et al*. Positional modification techniques for supine obstructive sleep apnea: A systematic review and meta-analysis. *Sleep Med Rev* 2017;36:107–15.
8 Mok Y, Tan A, Hsu PP, *et al*. Comparing treatment effects of a convenient vibratory Positional device to CPAP in Positional OSA: a crossover randomised controlled trial. *Thorax* 2020;75:331–7.
9 Beyers J, Vanderveken OM, Kastoer C, *et al*. Treatment of sleep-disordered breathing with Positional therapy: long-term results. *Sleep Breath* 2019;23:1141–9.
10 Heinzer RC, Pellaton C, Rey V, *et al*. Positional therapy for obstructive sleep apnea: an objective measurement of patients' usage and efficacy at home. *Sleep Med* 2012;13:425–8.
11 Omobomi O, Quan SF. Positional therapy in the management of Positional obstructive sleep apnea-a review of the current literature. *Sleep Breath* 2018;22:297–304.
12 de Vries GE, Hoekema A, Doff MHJ, *et al*. Usage of Positional therapy in adults with obstructive sleep apnea. *J Clin Sleep Med* 2015;11:131–7.
13 Levendowski DJ, Seagraves S, Popovic D, *et al*. Assessment of a neck-based treatment and monitoring device for Positional obstructive sleep apnea. *J Clin Sleep Med* 2014;10:863–71.
14 Frank MH, Ravesloot MJL, van Maanen JP, *et al*. Positional OSA part 1: towards a clinical classification system for position-dependent obstructive sleep apnoea. *Sleep Breath* 2015;19:473–80.
15 Oksenberg A, Gadoth N. Are we missing a simple treatment for most adult sleep apnea patients? the avoidance of the supine sleep position. *J Sleep Res* 2014;23:204–10.
16 Bignold JJ, Deans-Costi G, Goldsworthy MR, *et al*. Poor long-term patient compliance with the tennis ball technique for treating Positional obstructive sleep apnea. *J Clin Sleep Med* 2009;5:428–30.
17 Eijsvogel MM, Ubbink R, Dekker J, *et al*. Sleep position Trainer versus tennis ball technique in Positional obstructive sleep apnea syndrome. *J Clin Sleep Med* 2015;11:139–47.
18 Marklund M, Verbraecken J, Randerath W. Non-CPAP therapies in obstructive sleep apnoea: Mandibular advancement device therapy. *Eur Respir J* 2012;39:1241–7.
19 van Maanen JP, de Vries N. Long-term effectiveness and compliance of Positional therapy with the sleep position Trainer in the treatment of Positional obstructive sleep apnea syndrome. *Sleep* 2014;37:1209–15.
20 de Ruiter MHT, Benoist LBL, de Vries N, *et al*. Durability of treatment effects of the sleep position Trainer versus oral appliance therapy in Positional OSA: 12-month follow-up of a randomized controlled trial. *Sleep Breath* 2018;22:451.
21 Hidalgo Armas L, Ingles S, Vaca R, *et al*. New forehead device in Positional obstructive sleep apnoea: a randomised clinical trial. *Thorax* 2021;76:930–8.
22 Benoist LBL, Verhagen M, Torensma B, *et al*. Positional therapy in patients with residual Positional obstructive sleep apnea after upper airway surgery. *Sleep Breath* 2017;21:279–88.
23 Benoist L, de Ruiter M, de Lange J, *et al*. A randomized, controlled trial of Positional therapy versus oral appliance therapy for position-dependent sleep apnea. *Sleep Med* 2017;34:109–17.
24 Levendowski D, Cunnington D, Swieca J, *et al*. User compliance and behavioral adaptation associated with supine avoidance therapy. *Behav Sleep Med* 2018;16:27–37.
25 Laub RR, Tønnesen P, Jennum PJ. A sleep position Trainer for Positional sleep apnea: a randomized, controlled trial. *J Sleep Res* 2017;26:641–50.
26 Beyers J, Dieltjens M, Kastoer C, *et al*. Evaluation of a trial period with a sleep position Trainer in patients with Positional sleep apnea. *J Clin Sleep Med* 2018;14:575–83.
27 Buyse B, Ciordas S, Hoet F, *et al*. Positional obstructive sleep apnoea: challenging findings in consecutive patients treated with a vibrating position Trainer. *Acta Clin Belg* 2019;74:405–13.
28 van Maanen JP, Meester KAW, Dun LN, *et al*. The sleep position Trainer: a new treatment for Positional obstructive sleep apnoea. *Sleep Breath* 2013;17:771–9.
29 Bignold JJ, Mercer JD, Antic NA, *et al*. Accurate position monitoring and improved supine-dependent obstructive sleep apnea with a new position recording and supine avoidance device. *J Clin Sleep Med* 2011;7:376–83.
30 Dieltjens M, Vroegop AV, Verbruggen AE, *et al*. A promising concept of combination therapy for Positional obstructive sleep apnea. *Sleep Breath* 2015;19:637–44.
31 Benoist LBL, Vonk PE, de Vries N, *et al*. New-generation Positional therapy in patients with Positional central sleep apnea. *Eur Arch Otorhinolaryngol* 2019;276:2611–9.
32 van Kesteren ER, van Maanen JP, Hilgevoord AAJ, *et al*. Quantitative effects of trunk and head position on the apnea Hypopnea index in obstructive sleep apnea. *Sleep* 2011;34:1075–81.
33 Tate A, Kurup V, Shenoy B, *et al*. Influence of head flexion and rotation on obstructive sleep apnea severity during supine sleep. *J Sleep Res* 2021;30.
34 Sabil A, Blanchard M, Trzepizur W, *et al*. Positional obstructive sleep apnea within a large multicenter French cohort: prevalence, characteristics, and treatment outcomes. *J Clin Sleep Med* 2020;16:2037–46.

35 Weaver TE, Sawyer AM. Adherence to continuous positive airway pressure treatment for obstructive sleep apnoea: implications for future interventions. *Indian J Med Res* 2010;131:245–58.
36 Pascoe M, Bena J, Andrews ND, *et al*. Dose-response relationship between positive airway pressure therapy and excessive daytime Sleepiness: the Homepap study. *J Clin Sleep Med* 2022;18:1027–34.
37 Corrigan J, Tsai WH, Ip-Buting A, *et al*. Treatment outcomes among rural and urban patients with obstructive sleep apnea: a prospective cohort study. *J Clin Sleep Med* 2022;18:1013–20.