Sleep Position Trainer
Information for physicians

- Product brochure
- Scientific background
- Abstracts of clinical papers
- Paper: Long-Term effectiveness and compliance of positional therapy for OSA
- Paper: A promising concept of combination therapy for positional obstructive sleep apnea
- Poster presentations
Sleep Position Trainer
The best treatment for Positional OSAS
“Innovation distinguishes between a leader and a follower.”

- Steve Jobs
Positional Obstructive Sleep Apnea Syndrome (POSAS) is caused by gravitational forces on the tongue, soft palate and throat, resulting in repeated collapse of the airway during sleep, reducing oxygen saturation in the blood. The severity varies per patient and determines what kind of treatment the patient requires.

\[
\text{POSAS} = \text{AHI supine} > 2 \times \text{AHI non-supine}
\]

POSAS is defined as OSAS where the Apnea Hypopnea Index (AHI) level is at least twice as high during supine sleep compared to the AHI during sleep in all other positions.

- 56% of mild and moderate OSAS patients have POSAS (Richard, 2006)
- 30% have a higher supine AHI, but not twice as high (Richard, 2006)

Prevalence of POSAS patients worldwide (estimated)

- 73.4 million mild
- 15.7 million moderate
- 6.7 million severe

6.4% of the population is suffering from OSAS (Eijsvogel, 2012)

**Patient selection:**
For successful treatment with Positional Therapy, the following conditions should apply to your patient.

- Mild and moderate OSAS (AHI 5-30)
- Positional OSAS: AHI supine > 2x AHI non-supine
- Sleeping within 10-90% of the night supine
- Able to sleep in non-supine position (eg. no shoulder or specific back problems)
Sleep Position Trainer
The best treatment for Positional OSAS

How it works
The Sleep Position Trainer (SPT) measures the sleep behavior of the patient continuously. Once the patient turns in to the supine position, this normally happens during lighter sleeping stages, the SPT gives a gentle vibration. This reminds the patient to change its sleeping position, without disrupting the natural sleep architecture. The SPT is worn in a comfortable torso strap around the upper body. In addition, the SPT comes with software to analyze the progress of the treatment.

“I used the SPT myself for several weeks, and found the device quite comfortable, the SPT did not negatively affect my sleep at all.”
- David P. White, MD Clinical Professor of Medicine, Harvard Medical School.

SPT Comfort Program
The SPT Comfort Program helps the patient get used to sleep in a non-supine position by gradually reducing the amount of supine sleep. The first two nights the SPT only measures the sleep behavior. From the third to the tenth night, the SPT slowly builds up the amount of feedback. This improves the acceptance of the SPT by the patient.

Innovative features increase comfort of the SPT

• High compliance
• Easy to maintain
• Does not disrupt sleep
• Limited side effects
• Reversible
• Combination therapy possible

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Innovative features increase comfort of the SPT

• High compliance
• Easy to maintain
• Does not disrupt sleep
• Limited side effects
• Reversible
• Combination therapy possible
“I noticed a clear difference: I feel more energetic during daytime, I don’t fall asleep on the couch and feel less tired while driving.”

- J. Homan, patient, after sleeping with the SPT for one month.
Proven effective with high compliance

92.7% compliant to the SPT
(Van Maanen, 2013)

Highest mean disease alleviation (MDA)
A measure of the overall therapeutic effectiveness
(Eijsvogel, 2013; Vanderveken, 2013; Grote, 2000)

<table>
<thead>
<tr>
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<th>SPT</th>
<th>MRA</th>
<th>CPAP</th>
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<td>MDA (%)</td>
<td>70.5%</td>
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The SPT does not affect nor disrupt the sleep architecture of the patient
(Eijsvogel, 2013; Van Maanen, 2013)

Effective and well-tolerated treatment for POSAS patients

48% patients cured [AHI < 5]
(Van Maanen, 2013)

68.8% reduction on total AHI
(Van Maanen, 2013)

48.6% patients cured
(Van Maanen, 2014)

90.5% reduction in supine sleep
(Van Maanen, 2014)

The SPT makes other therapies more effective
52.1% improved reduction of AHI when SPT is added to a Mandibular Repositioning Appliance (MRA) treatment.
(Dieltjens, 2014)

The SPT has been clinically tested in over 35,000 nights

With the SPT the supine sleep is reduced to an average of 3% supine sleep, this effect is maintained after six months
(Van Maanen, 2014)
Read out patient data with SPT Connect software

The SPT measures the sleep behavior of the patient continuously and stores the information in its internal memory. Patients can analyze the comprehensive overview of the sleep data gathered by the SPT with the use of our SPT Connect software for Windows. Physicians can easily generate sleep reports with the separate supplied software for specialists. These reports provide an overview of the effectiveness, compliance and overall progress of the treatment.

Numbers tell the tale
Analyze your patient’s treatment progress with our SPT Connect software
“The SPT has potential to become a game changer.”
- Prof. dr. N. de Vries, a.o. member of guideline committees on obstructive sleep apnea.
SPT Experience
Sleep Position Trainer trial device

For Positional OSAS patients

Provide your patient with the opportunity to test the Sleep Position Trainer (SPT). Determine whether the SPT is a suitable treatment option for your patient by using the SPT Experience.

The SPT Experience is a device similar to the normal SPT with the exception that it will stop working after 28 nights. A SPT Experience report can be generated by a physician to analyze the sleep data of the patient. Based on the results the physician and the patient can conclude if the SPT is a suitable treatment option for the patient.

Rest for next use
Once the SPT Experience trial period is finished, the device can be reset and prepared for the next patient.

Sleep Position Trainer
The SPT measures the sleep behavior of the patient continuously. Once the patient turns into the supine position the SPT gives a gentle vibration. This reminds the patient to change their sleeping position, without disrupting their natural sleeping architecture. The device is worn in a comfortable torso strap around the upper body.
The sleep position trainer: a new treatment for positional obstructive sleep apnoea

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Abstract

Background Positional obstructive sleep apnoea (POSA), defined as a supine apnoea–hypopnoea index (AHI) twice or more as compared to the AHI in the other positions, occurs in 56 % of obstructive sleep apnoea patients. Positional therapy (PT) is one of several available treatment options for these patients. So far, PT has been hampered by compliance problems, mainly because of the usage of bulky masses placed in the back. In this article, we present a novel device for treating POSA patients.

Methods Patients older than 18 years with mild to moderate POSA slept with the Sleep Position Trainer (SPT), strapped to the chest, for a period of 29±2 nights. SPT measures the body position and vibrates when the patient lies in supine position.

Results Thirty-six patients were included; 31 patients (mean age, 48.1±11.0 years; mean body mass index, 27.0±3.7 kg/m²) completed the study protocol. The median percentage of supine sleeping time decreased from 49.9 % [20.4–77.3 %] to 0.0 % [range, 0.0–48.7 %] (p<0.001). The median AHI decreased from 16.4 [6.6–29.9] to 5.2 [0.5–46.5] (p<0.001). Fifteen patients developed an overall AHI below five. Sleep efficiency did not change significantly. Epworth Sleepiness Scale decreased significantly. Functional Outcomes of Sleep Questionnaire increased significantly. Compliance was found to be 92.7 % [62.0–100.0 %].

Conclusions The Sleep Position Trainer applied for 1 month is a highly successful and well-tolerated treatment for POSA patients, which diminishes subjective sleepiness and improves sleep-related quality of life without negatively affecting sleep efficiency. Further research, especially on long-term effectiveness, is ongoing.

Keywords Positional therapy · Positional · OSA · Obstructive sleep apnoea

Abbreviations

AHI Apnoea–hypopnoea index
CPAP Continuous positive airway pressure
ESS Epworth Sleepiness Scale
FOSQ Functional Outcomes of Sleep Questionnaire
OSA Obstructive sleep apnoea
POSA Positional obstructive sleep apnoea
PSG Polysomnography
PT Positional therapy
SD Standard deviation
SPT Sleep Position Trainer
Obstructive sleep apnoea (OSA) is a prevalent disorder which is estimated to affect about 4% of men and 2% of women [1] and is associated with increased cardiovascular morbidity and mortality [2, 3]. More than half of OSA patients appear to have position-dependent OSA (POSA), defined as an apnoea-hypopnoea index (AHI) during sleep in supine position that is at least twice as high as the AHI during sleep in other positions [4–7].

The therapeutic armamentarium for OSA comprises several treatment options. Continuous positive airway pressure (CPAP) is often regarded as the gold standard in the treatment of moderate and severe cases. Oral appliances and upper airway surgery are both used in mild and moderate cases or in reserve of CPAP failure. In all patients with OSA, conservative approaches including abstinence from alcohol and sedatives, weight reduction, quitting smoking and avoidance of the supine sleeping position in POSA should be considered [8]. Positional therapy (PT) is a treatment modality which aims at preventing patients from sleeping in the worst position, which is, in most cases, the supine position [9]. The role of positional therapy as a minimally invasive treatment modality in patients with positional OSA looks promising [10]. The effectiveness of positional therapy in positional OSA has been tested since the 1980s [11]. The tennis ball technique, where a tennis ball is placed in the centre of the back, was one of the first described positional therapies and has been shown to be effective in normalizing AHI in positional OSA patients. Several variations of the tennis ball technique (positional alarms, verbal instructions, vests, special pillows) have also been tested with similarly good results [8, 12–25]. However, the clinical significance of positional therapy is so far hampered by a very low compliance rate which ranges from 40%, short term, to 10%, long term [15, 19, 20]. These results show the need for a positional therapy system that is able to ensure high compliance in patients suffering from POSA and which can improve the discomfort and disruption of the sleep architecture, both being the reason for the poor compliance seen in the past. To this end, we recently presented a novel treatment concept for POSA—a simple small neck-worn vibrating device which corrected patients when adopting the supine position. This novel concept has been shown to be effective in significantly reducing the AHI without disrupting the sleep quality [25].

In line with this technology and its encouraging results, a new medical device appropriate for wide clinical use was developed—the Sleep Position Trainer (SPT). With the SPT developed, this study aims to investigate the viability of this new vibrating device as a reliable treatment option for patients with POSA. The hypothesis for this study states that this device presents good objective and subjective effects (respectively measured with polysomnographies and questionnaires) with a high compliance and without negatively affecting the sleep efficiency.

Methods

Study subjects

From June 2011 through January 2012, patients who were referred to the Department of Otorhinolaryngology, Head and Neck Surgery of the Saint Lucas Andreas Hospital (Amsterdam, the Netherlands) for suspected sleep disordered breathing were considered eligible if they met the following inclusion criteria: (1) age of 18 years or older, (2) AHI between 5 and 30 events/h at a baseline polysomnography, (3) positional sleep apnoea defined as an AHI in supine position greater than two times the AHI in non-supine positions, (4) the percentage of total sleep time in supine position was between 20 and 90%, (5) the percentage of central apnoeas was less than 50% of the total amount of apnoeas, (6) no medical history with known causes of daytime tiredness or sleep disruption (shift working, neurologic disorders, insomnia, periodic leg movement syndrome, narcolepsy, etc.) and (7) no cardiac pacemaker. Exclusion criteria were: (1) use of other treatment modalities for OSA during the course of the study and (2) unwillingness or inability to participate in all aspects of the study. All patients signed an informed consent. The study was approved by the institution’s ethics committee.

Study protocol/design

All patients underwent two polysomnographic assessments. The baseline assessment consisted of an overnight polysomnography (PSG) to confirm the diagnosis of POSA. Within 28 days after the baseline PSG, patients started using the SPT for 29±2 nights. On day 1, patients filled out the Epworth Sleepiness Scale (ESS) [26] and the Functional Outcomes of Sleep Questionnaire (FOSQ) [27] to assess their daytime sleepiness and quality of life.

Treatment with the SPT was divided into three phases: a diagnostic phase, a training phase and a therapy phase. The first two nights were defined as the diagnostic phase, where the SPT monitored and recorded the sleeping position and in which no active feedback was given to the patient. The following seven nights entailed the training phase, where the SPT began to vibrate in an increasing amount of
episodes of supine sleep. From night 10 onwards, the therapy phase started in which the SPT vibrated every time a supine sleeping position was detected in order to urge the patient to change his or her sleeping position. To promote continued use, subjects could upload and read out information about their nightly behaviour (e.g. percentages of different sleeping positions) to their own personal computer at any desired time.

The last assessment took place after 29±2 days and included a PSG whilst using the SPT. Additionally, ESS and FOSQ questionnaires were completed for a second time.

The Sleep Position Trainer device

The SPT is a small, lightweight device (72×35×10 mm, 25 g) which is worn around the chest in a neoprene strap (Fig. 1). The neoprene strap comprises a pocket in which the device is placed on the sternum and can be closed with a Velcro tab. The device measures the orientation using a three-dimensional digital accelerometer. The measurements were used to define the posture of the user: left side, right side, supine, prone or upright. The device responded to the supine position with a vibration stimulus to provide feedback to the user. The stimulus started after the supine position was detected, and no turning movement was detected anymore. The device continued with a gradually increasing strength and stimulus duration, until non-supine position was detected. If the patient did not react to the stimulus, the vibrations would be paused to be reinitiated after 2 min. Furthermore, the SPT provided an internal memory to store the sleeping posture of the user for a period of at least 90 days. The device employs a USB port to communicate data to a personal computer and to recharge the integrated battery.

Polysomnography

A full-night diagnostic polysomnography (EMBLA® A10/Titanium, Medcare Flaga, Iceland, and Somnoscreen™, SOMNOmedics GmbH, Randersacker, Germany) was performed in each subject. To determine the stages of sleep, an electroencephalogram (Fp2, C4, O2), electro-oculogram and electromyogram of the submentalis muscle were obtained. Nasal airflow was measured by a nasal cannula/pressure transducer inserted in the opening of the nostrils. Arterial blood oxyhaemoglobin was recorded with the use of a finger pulse oximeter. Thoracoabdominal excursions were measured qualitatively by respiratory effort belts placed over the rib cage and abdomen. Snoring was recorded through a piezo snoring sensor. Body position was determined by a position sensor, which differentiated between the upright, left side, right side, prone and supine positions. Limb movements were detected with an anterior tibial electromyogram. Electrocardiogram was also measured using two electrodes posted on the collarbone. All signals were recorded with digital sampling, digital filtering, digital storage recording technology, permitting a sample efficiency of 90 % and a sample rate up to 200 Hz. Storage was done on a PCMCIA flash card. The following day, data were downloaded to the computer and analysed by dedicated sleep software (Somnologica™, Broomfield, USA; DOMINO, SOMNOmedics GmbH, Randersacker, Germany). The data were manually reviewed for analysis by an experienced sleep investigator.

Analysis and definitions

The sleep stages were scored manually in 30-s epochs according to American Academy of Sleep Medicine (AASM) criteria, with N3 reflecting slow wave sleep or Rechtschaffen and Kales stages 3 and 4 [28]. Obstructive respiratory events were analysed according to the AASM criteria [28]. As such, obstructive apnoea was defined as a decrease of airflow of more than 90 % for at least 10 s, in the presence of respiratory efforts. Central apnoea was defined as a decrease of airflow of more than 90 % for at least 10 s and no respiratory effort of the thorax or abdomen. Hypopnoea was defined as a decrease of airflow of 30–90 % for at least 10 s, with a continuation of respiratory effort and leading to a decrease in haemoglobin saturation of at least 3 %. The number of apnoea and hypopnoea episodes per hour of sleep is referred to as the AHI. Obstructive sleep apnoea was diagnosed if the AHI was >5 [28]. Sleep efficiency was defined as the total sleep time/time in bed.

Based on Sher's criteria of surgical success [29], SPT success was defined as a post-treatment AHI of less than 20 events/h along with at least 50 % decrease from the baseline AHI (responders). Treatment failure was defined as a post-treatment decrease of AHI from baseline of less than 50 % (non-responders).

SPT compliance, in line with the CPAP compliance definition [30], was defined as the use of the SPT for at least 4 h per night, seven nights per week.
Statistical analysis

Statistical analysis was performed using SPSS (version 15, SPSS Inc, Chicago, IL). Quantitative data are reported as mean±SD or as median [range]. Comparison of data between baseline and after 1 month of SPT use was carried out using the paired t test in the case of normally distributed data and the Wilcoxon test in the case of skewed data. Data obtained during the three different phases (i.e. diagnostic, training and therapy) were compared with Friedman's test for repeated measures. A p value of <0.05 was considered to indicate statistical significance.

Results

Thirty-six patients who met the inclusion criteria were included in the study. Thirty-one patients completed the study protocol. Five patients withdrew, three patients because of lack of motivation and two patients because of back and shoulder complaints.

The remaining 31 patients (27 males; mean age, 48.1±11.0 years; mean body mass index, 27.0±3.7 kg/m) finished the study uneventfully. The median compliance rate was 92.7 % (range, 62 to 100 %). The polysomnographical and clinical characteristics of patients at baseline and after 1 month of SPT are shown in Table 1. As the results show, not only the total AHI but also the AHI in supine position as well as the percentage of sleep time spent in supine position, desaturation index, apnoea index and ESS score presented significant decrease, whereas minimum oxygen desaturation, the percentage of sleep time spent in non-supine position and FOSQ score exhibited significant increase. Sleep efficiency did not change significantly. Individual values of the apnoea–hypopnoea index, the percentage of time spent in supine position, ESS and FOSQ scores at baseline and after 1 month of positional therapy are shown in Table 2.

Twenty-two patients were considered responders (71.0 %) and 9 non-responders (29.0 %). The clinical and polysomnographical characteristics of responders and non-responders are presented in Table 3. AHI, apnoea index, desaturation index, supine AHI and Epworth Sleepiness Scale score all significantly decreased in the responder group. Furthermore, average oxygen saturation, minimum oxygen saturation and FOSQ score significantly increased in the responder group. In the non-responder group, a significant increase was seen in non-supine AHI. In both responders and non-responders, a significant increase in percentage non-supine position sleeping

| Table 1 Polysomnographical and clinical variables of the study group at baseline and after 1 month of SPT therapy (n=31) |
|---|---|---|
| Age, years | 48.1±11.0 | 27.0±3.7 |
| Male sex, % | 87.1 | 92.7 [62.0–100.0] |
| BMI | 27.0±3.7 | 27.4±4.0 |
| Compliance rate, % | 92.7 [62.0–100.0] | 0.387 |
| AHI, events/h | 16.4 [6.6–29.9] | 5.2 [0.5–46.5] |
| AHI in supine, events/h | 35.7 [9.3–81.0] | 0.0 [0.0–100.7] |
| AHI in non-supine, events/h | 3.2 [0.0–16.2] | 4.3 [0.1–48.0] |
| Average oxygen saturation, % | 95.1±1.4 | 95.5±1.6 |
| Minimum oxygen desaturation, % | 84.5±4.1 | 88.4±3.6 |
| Desaturation index, events/h | 11.2 [2.2–22.4] | 5.2 [0.9–39.6] |
| Apnoea index, events/h | 11.4 [1.0–26.3] | 2.5 [0.0–21.3] |
| Arousal index, events/h | 6.1 [0.0–28.4] | 5.5 [0.0–22.8] |
| Number of awakenings | 4.0 [0.0–60.0] | 3.0 [0.0–10.0] |
| Total sleep time, min | 456±76 | 429±87 |
| N2 sleep/total sleep time, % | 52.0±8.7 | 50.0±12.1 |
| N3 sleep/total sleep time, % | 22.4±9.8 | 21.7±7.7 |
| REM sleep/total sleep time, % | 19.5±5.6 | 20.9±6.4 |
| Sleep efficiency, % | 89.1 [61.1–99.7] | 89.4 [58.0–98.6] |
| Percentage supine | 49.9 [20.4–77.3] | 0.0 [0.0–48.7] |
| Percentage non-supine position | 50.1 [22.7–79.6] | 100.0 [51.3–100.0] |
| ESS score | 11 [2–20] | 9 [0–19] |
| FOSQ score | 86.0±22.1 | 93.8±21.7 |

Data are presented either as mean±SD or as median [range]

SPT Sleep Position Trainer
time and a significant decrease in percentage of supine position sleeping time were seen. The percentage of N3 or deep sleep did not change significantly during SPT therapy. Responders had a significantly lower AHI, desaturation index and apnoea index than non-responders after SPT ($p<0.001$, $p=0.004$ and $p=0.001$). Non-responders had a significantly higher non-supine AHI and significantly lower number of awakenings than responders after SPT ($p<0.001$ and $p=0.008$).

Figures 2 and 3 show the effect of SPT on, respectively, the percentage of supine position and AHI. Post hoc analyses showed that the decrease between diagnostic and training phases was highly significant ($p<0.001$), as was the case for the decrease between diagnostic and therapy phases and between training and therapy phases (data not shown here).

### Discussion

If one would set requirements for an ideal (P)OSA treatment, it would be effective and well tolerated, it would not disturb sleep or would even improve it, it would be reversible and it would have negligible side effects, at acceptable costs. The analysis of more than 900 sleep nights in this study indicates that the SPT fulfils these six criteria to a high degree.

This study shows that the SPT is highly effective in the treatment of POSA. The percentage of time slept in supine position decreased significantly, with a median of 0%.

### Table 2

<table>
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<th>Patient no.</th>
<th>AHI Baseline</th>
<th>AHI After SPT</th>
<th>% supine position Baseline</th>
<th>% supine position After SPT</th>
<th>ESS Baseline</th>
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Table 3  Anthropometrical data and clinical and polysomnographic variables in responders and non-responders at baseline and after 1 month

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<tr>
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<th>Responders (n=22)</th>
<th>After SPT</th>
<th>p value&lt;sup&gt;a&lt;/sup&gt;</th>
<th>Non-responders (n=9)</th>
<th>After SPT</th>
<th>p value&lt;sup&gt;a&lt;/sup&gt;</th>
<th>p value&lt;sup&gt;b&lt;/sup&gt;</th>
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<td>Baseline</td>
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<td>Baseline</td>
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<tr>
<td>Age, years</td>
<td>49.8±11.6</td>
<td></td>
<td></td>
<td>44.1±8.6</td>
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<tr>
<td>Male sex, %</td>
<td>86.4</td>
<td></td>
<td></td>
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<tr>
<td>BMI</td>
<td>27.3±3.4</td>
<td></td>
<td></td>
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<td>Compliance rate, %</td>
<td>92.9 [61.5–100.0]</td>
<td></td>
<td>&lt;0.001</td>
<td>96.4 [72.4–100.0]</td>
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<tr>
<td>AHI, events/h</td>
<td>16.2 [6.6–29.9]</td>
<td>3.9 [0.5–10.3]</td>
<td>&lt;0.001</td>
<td>18.2 [6.7–21.0]</td>
<td>14.1 [4.9–46.5]</td>
<td>0.214</td>
<td>&lt;0.001</td>
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<tr>
<td>AHI in supine, events/h</td>
<td>36.5 [9.3–81.0]</td>
<td>0.0 [0.0–37.3]</td>
<td>&lt;0.001</td>
<td>34.7 [14.9–63.6]</td>
<td>0.0 [0.0–100.7]</td>
<td>0.173</td>
<td>0.685</td>
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<tr>
<td>AHI in non-supine, events/h</td>
<td>3.2 [0.0–16.2]</td>
<td>3.2 [0.1–9.6]</td>
<td>0.833</td>
<td>3.7 [0.2–9.1]</td>
<td>10.1 [3.5–48.0]</td>
<td>0.011</td>
<td>&lt;0.001</td>
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<tr>
<td>Average oxygen saturation, %</td>
<td>95.0±1.5</td>
<td>95.5±1.4</td>
<td>0.004</td>
<td>95.4±1.0</td>
<td>95.2±2.0</td>
<td>0.681</td>
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<tr>
<td>Minimum oxygen desaturation, %</td>
<td>84.4±4.5</td>
<td>89.4±2.3</td>
<td>&lt;0.001</td>
<td>84.7±3.4</td>
<td>86.0±5.1</td>
<td>0.431</td>
<td>0.087</td>
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<td>Desaturation index, events/h</td>
<td>11.2 [2.2–22.4]</td>
<td>4.6 [0.9–13.1]</td>
<td>&lt;0.001</td>
<td>11.6 [5.5–19.0]</td>
<td>8.5 [3.4–39.6]</td>
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<td>0.044</td>
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<td>Apnoea index, events/h</td>
<td>11.0 [2.2–26.3]</td>
<td>1.8 [0.0–7.3]</td>
<td>&lt;0.001</td>
<td>8.0 [1.0–19.4]</td>
<td>8.3 [1.6–21.3]</td>
<td>0.953</td>
<td>0.001</td>
</tr>
<tr>
<td>Arousal index, events/h</td>
<td>7.5 [3.0–28.4]</td>
<td>5.2 [0.0–20.5]</td>
<td>0.027</td>
<td>0.0 [0.0–18.5]</td>
<td>6.5 [0.0–22.8]</td>
<td>0.176</td>
<td>0.203</td>
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<tr>
<td>Number of awakenings</td>
<td>3.5 [0.0–60.0]</td>
<td>4.0 [1.0–10.0]</td>
<td>0.659</td>
<td>4.0 [0.0–15.0]</td>
<td>1.0 [0.0–9.0]</td>
<td>0.068</td>
<td>0.008</td>
</tr>
<tr>
<td>Total sleep time, min</td>
<td>466±80</td>
<td>433±94</td>
<td>0.218</td>
<td>432±63</td>
<td>418±68</td>
<td>0.666</td>
<td>0.656</td>
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<tr>
<td>N2 sleep/total sleep time, %</td>
<td>49.8±8.2</td>
<td>47.3±12.2</td>
<td>0.366</td>
<td>57.3±8.0</td>
<td>56.6±9.5</td>
<td>0.700</td>
<td>0.051</td>
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<tr>
<td>N3 sleep/total sleep time, %</td>
<td>24.7±9.3</td>
<td>23.6±7.4</td>
<td>0.518</td>
<td>16.7±8.8</td>
<td>17.1±6.8</td>
<td>0.846</td>
<td>0.032</td>
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<tr>
<td>REM sleep/total sleep time, %</td>
<td>19.3±5.9</td>
<td>21.0±7.1</td>
<td>0.348</td>
<td>20.1±5.1</td>
<td>20.6±4.4</td>
<td>0.858</td>
<td>0.891</td>
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<tr>
<td>Sleep efficiency, %</td>
<td>88.6 [61.1–99.7]</td>
<td>86.1 [58.0–98.6]</td>
<td>0.306</td>
<td>89.1 [70.1–96.0]</td>
<td>92.0 [68.9–98.1]</td>
<td>0.594</td>
<td>0.086</td>
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<tr>
<td>Percentage supine</td>
<td>50.9 [20.4–77.3]</td>
<td>0.0 [0.0–36.3]</td>
<td>&lt;0.001</td>
<td>40.5 [21.4–71.1]</td>
<td>0.1 [0.0–48.7]</td>
<td>0.008</td>
<td>1.000</td>
</tr>
<tr>
<td>Percentage non-supine position</td>
<td>49.2 [22.7–79.6]</td>
<td>100.0 [63.7–100.0]</td>
<td>&lt;0.001</td>
<td>59.5 [29.0–78.6]</td>
<td>99.9 [51.3–100.0]</td>
<td>0.008</td>
<td>0.881</td>
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<td>ESS score</td>
<td>12 [3–20]</td>
<td>9 [1–19]</td>
<td>0.007</td>
<td>9 [2–18]</td>
<td>7 [0–19]</td>
<td>0.291</td>
<td>0.623</td>
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<tr>
<td>FOSQ core</td>
<td>84.4±23.6</td>
<td>94.8±21.8</td>
<td>&lt;0.001</td>
<td>90.0±18.6</td>
<td>91.6±22.6</td>
<td>0.710</td>
<td>0.715</td>
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</tbody>
</table>

Data are presented either as mean±SD or as median [range]

*SPT* Sleep Position Trainer

<sup>a</sup>Comparing baseline values with values after SPT per group responders/non-responders

<sup>b</sup>Comparing responders with non-responders after SPT
Six out of nine non-responders had an AHI reduction between 20 and 50%. With this novel treatment, 15 patients dropped in AHI value below five and had their (P)OSA cured (Table 2). The study of van Maanen et al. [25] showed a 60% success rate with a decrease of 53.8% in AHI value. The mean reduction in AHI was similar in both studies. Apparently, the location of the device, neck or chest, and duration of usage do not influence the average reduction in AHI. Table 4 shows the comparison between the first-generation device and the SPT.

Even the most effective medical devices only form a successful treatment when used properly. CPAP is used in moderate and severe OSA. Many patients refuse or simply cannot tolerate CPAP; about 25% of patients quit the probationary period [31]. Others use CPAP for a few hours per night, every night or incidentally [32]. Treatment with oral appliances is reasonably effective in mild and moderate OSA and snoring but can have negative side effects such as jaw discomfort, hypersalivation or dry mouth, while in the long term, dental occlusion might change. In addition, up to one third of patients have contraindications for using oral appliances [33].

In this study, compliance was defined as the use of the SPT for at least 4 h per night, seven nights a week, in line with the CPAP compliance definition [30]. The compliance, in a study period of 29±2 nights, was 92.7% [62–100%], which is an exceptionally high rate in comparison to CPAP, oral device therapy or to other studies which researched compliance in positional therapy. Ineffectiveness, backaches, discomfort and no improvement in sleep quality or daytime alertness have been responsible for poor compliance in positional therapy in the past. In this study, compliance was enhanced by using a very small, comfortably fitting device with optimal physical movement freedom. Increased comfort was further supported by several algorithms like a sleep-in period and a training programme so that patients gradually could get used to sleeping in non-supine positions. In addition, patients were able to check their progress by viewing the data on their nightly behaviour on a personal computer. Improving compliance in PT is a

![Fig. 2 Effect of SPT therapy on percentage of supine sleeping time.](image)

![Fig. 3 Effect of SPT therapy on AHI.](image)

Table 4 Comparison of first-generation device and SPT

<table>
<thead>
<tr>
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<th>SPT</th>
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<tr>
<td>Device placement</td>
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<td>Chest (strapped)</td>
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<td>Vibrational stimulus</td>
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<td>Yes</td>
</tr>
<tr>
<td>Timing vibrational stimulus</td>
<td>After 30 s</td>
<td>Directly</td>
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<tr>
<td>Varying in frequency</td>
<td>No</td>
<td>Yes</td>
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<tr>
<td>Varying in amplitude</td>
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<td>Yes</td>
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<tr>
<td>Training programme</td>
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<td>Yes</td>
</tr>
<tr>
<td>Start delay</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Data viewing feedback system</td>
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moderate POSA [24]. Also, positive predictions have been made about the learning effect of PT. Cartwright et al. suggested that patients may learn to avoid the supine position following PT and therefore do not need to use PT on a regular basis. Others may need PT either periodically to reinforce training or consistently to ensure non-supine sleep [11].

As discussed briefly in an earlier section, compliance is very likely related to improvement in sleep quality, daytime alertness and treatment comfort. Sleep efficiency was not disrupted by the use of the SPT nor was the percentage of deep sleep. Arousal index and number of awakenings both showed a non-significant decrease. Subjective parameters like the ESS showed a significant decrease, whereas the FOSQ significantly increased, which means that patients experienced less daytime sleepiness and a higher level of sleep-related quality of life. This finding, the significant effect on ESS and FOSQ scoring, partly might be influenced by the feedback from the device (for example, a computer readout of the percentage of supine sleep time) when using the therapy.

Due to the built-in training period of the SPT, patients can gradually get used to the lateral and prone positions. However, 2 out of 36 patients suffered from back and shoulder complaints and consequently discontinued SPT therapy. Fortunately, when a patient has no beneficial effects or has side effects of the device, the treatment is reversible without harming the patient, unlike surgery. Another advantage is the acceptable costs for the SPT. It is a one-time purchase, which is expected to be cheaper than CPAP. In case CPAP or PT is ineffective, it presumably can be returned to the distributor. Oral devices, however, are custom made and in case of failure cannot be returned and used by another patient.

There are some limitations of this study that need to be addressed. First of all, the average percentage of total time spent in supine position changed significantly from 45.6 to 53.3%, with a median of 0%; 16 out of 31 patients did not sleep in the supine position anymore using the SPT. One of the reasons the average percentage did not reach zero might be the finding that two patients did not respond very well to the stimulus; they were able to sleep in supine position for 48.7 and 36.3% of total sleep time (Table 2). Sleep position was measured in position sensors placed on the trunk (one for the PSG, one for the SPT). The finding that the occurrence of obstructive sleep apnoea depends not solely on the position of the trunk but also on the position of the head has already been discussed earlier by van Kesteren et al. [34]. Also, in patient 19 (Table 2), it would have been interesting to have investigated the position of the head in the polysonmographies as the AHI in lateral position was much higher in the second PSG compared to the first PSG (data not shown here), whilst percentage of supine sleep time significantly decreased.

As described in the literature, long-term results are disappointing in PT because of lack of compliance. In this study, patients used the SPT for 29±2 days; therefore, long-term (>6 months) effects, compliance, side effects and benefits are yet unknown. The data of this study showed that some people learned to avoid the supine position rapidly, while others did not seem to have such a therapeutical effect, or at least not within the study period of 1 month. Further research is ongoing, concentrating on long-term compliance and data collection from a larger group of subjects.

This study shows that the Sleep Position Trainer applied for 1 month (1) cures (P)OSA in 48 % of patients (15 of 31), (2) is a well-tolerated treatment for patients with positional OSA with a high compliance, 92.7% [62.0–100.0 %], (3) is associated with a response rate of 71.0 % and a median decrease of AHI of 61.1 % (in subjects who completed the 1-month study), (4) reduces the percentage of total sleeping time spent in the supine position to a median of 0, (5) does not negatively affect sleep quality and (6) diminishes subjective sleepiness and improves sleep-related quality of life.

In conclusion, it appears that the SPT applied for 1 month is a highly successful and well-tolerated treatment for patients with positional OSA, which diminishes subjective sleepiness and improves sleep-related quality of life without disrupting sleep quality. Further research, especially on long-term results, is ongoing.

Conflict of interest None of the authors have financial or other relationships that might lead to a conflict of interest.

References

patients with severe nonpositional obstructive sleep apnea. Chest 118:1018–1024
Long-Term Effectiveness and Compliance of Positional Therapy with the Sleep Position Trainer in the Treatment of Positional Obstructive Sleep Apnea Syndrome

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Department of Otolaryngology/Head Neck Surgery, Sint Lucas Andreas Hospital, Amsterdam, the Netherlands

Study Objectives: To investigate effectiveness, long-term compliance, and effects on subjective sleep of the Sleep Position Trainer (SPT) in patients with position-dependent obstructive sleep apnea syndrome (POSAS).

Design: Prospective, multicenter cohort study.

Patients or Participants: Adult patients with mild and moderate POSAS were included.

Interventions: Patients were asked to use the SPT for 6 mo. At baseline and after 1, 3, and 6 mo, questionnaires would be completed: Epworth Sleepiness Scale (ESS), Pittsburgh Sleep Quality Index (PSQI), Functional Outcomes of Sleep Questionnaire (FOSQ), and questions related to SPT use.

Measurements and Results: One hundred forty-five patients were included. SPT use and SPT data could not be retrieved in 39 patients. In the remaining 106 patients, median percentage of supine sleep decreased rapidly during SPT’s training phase (day 3 to 9) to near-total avoidance of supine sleep. This decrease was maintained during the following months of treatment (21% at baseline versus 3% at 6 mo). SPT compliance, defined as more than 4 h of nightly use, was 64.4%. Regular use, defined as more than 4 h of usage over 5 nights/w, was 71.2%. Subjective compliance and regular use were 59.8% and 74.4%, respectively. Median ESS (11 to 8), PSQI (8 to 6), and FOSQ (87 to 103) values significantly improved compared with baseline.

Conclusions: Positional therapy using the Sleep Position Trainer (SPT) effectively diminished the percentage of supine sleep and subjective sleepiness and improved sleep related quality of life in patients with mild to moderate position-dependent obstructive sleep apnea syndrome. SPT treatment appeared to have sustained effects over 6 months. SPT compliance and regular use rate were relatively good. Subjective and objective compliance data corresponded well. The lack of a placebo-controlled group limited the efficacy of conclusions.

Keywords: OSAS, position dependency, positional therapy, SPT, treatment

Citation: 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(7):1209-1215.

INTRODUCTION

Obstructive sleep apnea syndrome (OSAS) is the most prevalent type of sleep disordered breathing. It affects 4% of middle-aged men and 2% of middle-aged women1 and is associated with an increased risk of traffic accidents,2 an increased cardiovascular disease risk and an increase in all-cause mortality.3 Positional obstructive sleep apnea syndrome (POSAS) occurs in approximately 56% of patients with OSAS4,5 and is defined as an apnea-hypopnea index (AHI) greater than 5 and an AHI in the supine position twice as high or more than when compared with AHI in nonsupine positions together with subjective complaints.6 POSAS correlates negatively with body mass index (BMI) and OSAS severity.7 Methods to avoid the supine sleeping position, i.e., positional therapy (PT), in whichever form, have a substantial influence on OSAS severity.8 PT with a bulky mass placed against the patient’s back has proved to be as effective as continuous positive airway pressure (CPAP) in reducing AHI in patients with mild (5 < AHI < 15) and moderate (15 < AHI < 30) POSAS.9 Recently, the Sleep Position Trainer (SPT), a new form of PT, has been introduced. It has been shown to reduce the average percentage of supine sleep time from 45.6% to 5.3% and to cure (defined by an AHI < 5.0) 48% of patients with mild and moderate POSAS. Furthermore, patients report that it is less bulky and more comfortable to wear.10,11

Most of the currently available prospective studies investigating PT in patients with POSAS have studied short-term effects on AHI and/or subjective sleep parameters during 1 day, week, or month of use.11–16 However, it is a clinical reality that most OSAS treatment options in which a device has to be applied (CPAP, mandibular advancement device (MAD), PT) suffer from long-term compliance problems and hence hamper therapeutic effectiveness.17–19

The aim of the current study was to investigate the effectiveness, long-term compliance, and effects on subjective sleep parameters in a group of patients with POSAS using the SPT for a period of 6 mo.

METHODS

Patients

From February through August 2012, participants were consecutively recruited from 18 major sleep clinics in the Netherlands for an implementation cohort study. Adult participants, in whom no longer than 3 mo earlier mild or moderate POSAS had been diagnosed by means of a polysomnography (PSG) and who could be followed up digitally and were computer literate, were included. Exclusion criteria included any prior (P)OSAS treatment, central sleep apnea, uncontrolled or serious illness (i.e., cancer, chronic heart failure (New York Heart Association (NYHA) class II and higher), chronic obstructive pulmonary disease (Global initiative for chronic Obstructive Lung Disease (GOLD)) class I or higher), or recent or active psychiatric illness.12

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The online inclusion system digitally sent the following question were downloaded to the computer and analyzed by dedicated Inclusion consisted of enrollment in an online database. A Dutch (GOLD) stage II and higher), any other comorbid sleep disorder (for example narcolepsy, parasomnia, periodic limb movement disorder, restless legs syndrome, or primary insomnia), seizure disorders, cardiac pacemaker, mental retardation, current psychiatric disorders (i.e. substance related disorders and psychotic, mood, anxiety, somatoform, factitious, impulse control and adjustment disorders), or physical problems causing inability to sleep on the side. The baseline visit consisted of a medical history and physical examination by the on-site physician investigator. Inclusion consisted of enrollment in an online database. A Dutch medical device distributor company contacted and visited the included patient to deliver the SPT and instruct the patient on its use. The patient was assigned an account online to upload SPT data after registration of his or her SPT in the online database. The online inclusion system digitally sent the following questionnaires to all registered subjects at baseline, and after the first, third, and sixth month of use: Epworth Sleepiness Scale (ESS, range 0-24), Pittsburgh Sleep Quality Index (PSQI, range 0-21), and the Functional Outcomes of Sleep Questionnaire (FOSQ, range 0-120). Patients would use the SPT for 6 mo and could keep their device after the study period ended. Patients could stop using the SPT at any time. This study was centrally approved by the Medical Ethics Committee (Amsterdam), followed by local committees. All participants signed informed consent prior to the initiation of any research activities.

Sleep Position Trainer

The SPT has been described earlier and consisted of a small, lightweight device (72 × 35 × 10 mm, 25 g) that was worn across the chest with a neoprene strap (Figure 1). The device used a three-dimensional digital accelerometer to determine body position. A video-based validation study by the manufacturer showed that SPT has an accuracy of 96.3% in the measurement of body position over 167 turns. Treatment with the SPT was divided into three phases: a diagnostic phase, a training phase, and a therapy phase. The first 2 nights were defined as the diagnostic phase, during which the SPT monitored and recorded the sleeping position and no active feedback was given to the patient. The following 7 nights entailed the training phase, during which the SPT began to vibrate in an increasing amount of episodes of supine sleep. Night 10 onward comprised the therapy phase, during which the SPT vibrated every time a supine sleeping position was detected in order to urge the patient to change his or her sleeping position. The vibration stimulus was adapted automatically in strength, pattern, and duration, until a nonsupine position was detected. If the patient did not react, the vibrations were paused and reinitiated after 2 min. Furthermore, the SPT provided an internal memory to store data on sleeping posture and a USB port to recharge the integrated battery and to communicate data to an online self-monitoring system, which also enabled distance monitoring by the patient’s physician.

Definitions

The criteria for OSAS included an AHI of 5 or more and evidence of daytime sleepiness. The AHI was defined as the mean number of apneas and hypopneas per hour during sleep, and an apnea as a period of 10 sec or more with a reduction of oronasal airflow of greater than 90%. Hypopnea was defined as an episode of greater than 30% reduced oronasal airflow for 10 sec or more accompanied by a decrease of 4% or more of the arterial oxyhemoglobin saturation. AHI thresholds were 5, 15, and 30 events per hour for mild, moderate, and severe levels of OSAS, respectively. POSAS was defined as an AHI of 5 or higher and an AHI in the supine position at least twice as high when compared to each of the AHI values found in the other positions. Effectiveness was defined in relation to percentage of supine sleep time. The SPT would be considered effective when the use of the device would provide a clinically significant reduction in percentage of supine sleep time. Compliance, in line with CPAP’s compliance definition, was defined as the continuous use of the SPT for at least 4 h per night, as an average over all nights observed. Additionally, regular SPT use was defined as at least 4 h of SPT usage on 70% of the days monitored, in line with CPAP’s criteria for regular use. Objective data on compliance were obtained through means of the SPT on a day-to-day basis. Subjective compliance was measured using online questionnaires after 1, 3, and 6 mo with the questions “How many hours do you use the SPT per night?” and “How many days per week do you use the SPT?”

Statistical Analysis

Changes in parameters before and after treatment were tested with the Wilcoxon signed rank test. A P value < 0.05 was considered to be significant. All statistical analyses were performed with SPSS 20.
performed with SPSS statistics software (version 20, IBM Corporation, Chicago, Illinois, USA). To evaluate the effects of SPT, a per-protocol analysis was performed.

RESULTS
A total of 145 patients with mild and moderate POSAS, who met the inclusion criteria, were initially included in our study and entered into the online database. Baseline patient characteristics of those 145 patients are shown in Table 1. All patients filled in the questionnaires (t = 0), which resulted in the baseline questionnaire scores depicted in Table 2. A patient flow diagram, filtering out to the sample’s full records list of 53 patients at t = 6, is depicted in Figure 2.

### Table 1—Patient characteristics at baseline inclusion polysomnography (n = 145)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Median</th>
</tr>
</thead>
<tbody>
<tr>
<td>AHI (h)</td>
<td>11.5 [9.0]</td>
</tr>
<tr>
<td>AHI supine (h)</td>
<td>28.2 [25.6]</td>
</tr>
<tr>
<td>% supine sleep</td>
<td>35.0 [29.0]</td>
</tr>
<tr>
<td>Age (y)</td>
<td>53 [14.3]</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>27.0 [4.0]</td>
</tr>
<tr>
<td>Ratio male : female</td>
<td>4.7 : 1</td>
</tr>
</tbody>
</table>

Values between brackets represent the interquartile range. AHI, apnea hypopnea index; BMI, body mass index.

### Table 2—Questionnaire values and percentage of supine sleep time during 6 months of Sleep Position Trainer (SPT) treatment for all available Sleep Position Trainer users

<table>
<thead>
<tr>
<th>Variable</th>
<th>t = 0 Median</th>
<th>t = 1 Median</th>
<th>t = 3 Median</th>
<th>t = 6 Median</th>
</tr>
</thead>
</table>

Values between brackets represent the interquartile range. ESS, Epworth Sleepiness Scale; FOSQ, Functional Outcomes of Sleep Questionnaire; PSQI, Pittsburgh Sleep Quality Index. Baseline (t = 0), one month (t = 1), 3 months (t = 3), 6 months (t = 6).

### Figure 2—Patient flow diagram. Baseline (t = 0), one month (t = 1), 3 months (t = 3), 6 months (t = 6).

Objective Compliance and Hours of Use
Of the initial 145 patients, neither SPT use nor SPT data could be retrieved in 39 of them because patients had not registered their SPT in the online database and were lost to follow-up. When reviewing inclusion data for these 39 patients, no significant differences could be found in terms of baseline patient characteristics when compared to the group of patients that registered their SPT. For the group of 106 patients that did upload their SPT data, the distribution of hours of SPT use is shown in Table 3. Median SPT use during 6 mo was 923 h (interquartile range [IQR] = 760), or 5.5 h on average per night for all nights. As shown in Table 4, 35 patients used the SPT during all 168 nights. Median SPT use for the 106 patients was...
163 of the 168 days (IQR = 98). Figure 3 shows the gradual decrease in the number of patients from whom SPT data could be retrieved and shows the eventual number of patients who were using the SPT and uploading the data during the full study period. Objective SPT compliance in this group of 106 patients, defined as more than 4 h of usage per night as an average over 168 nights, was 64.4%. Regular SPT use was 71.2% over all nights observed.

Effectiveness and Effect on Subjective Sleep Parameters

Figure 4 illustrates that the median percentage (and IQR) of supine sleep time, as measured by the SPT, quickly decreases from baseline to day 9 and that this reduced percentage of supine sleep is maintained over time. The SPT’s diagnostic and training (day 1 and 2, and 3 to 9, respectively) and therapeutic phase (from day 10 onward) can be clearly identified from Figure 4. Table 2 shows median questionnaire scores and percentage of supine sleep with IQR values for all available SPT users at the different time points. According to test-by-test exclusion approach on missing data, all parameters showed a significant decrease when compared to baseline. The median percentage of supine sleep time decreased significantly from 21% to 2% after 1 mo (Z = -8.015; P < 0.001), to 2% after 3 mo (Z = -7.473; P < 0.001) and to 3% after 6 mo (Z = -6.251; P < 0.001).

ESS values significantly decreased from 11 to 8 after 1 mo (Z = -6.291; P < 0.001), to 8 after 3 mo (Z = -6.647; P < 0.001), to 8 after 6 mo (Z = -6.749; P < 0.001). FOSQ significantly increased from 87 to 98 after 1 mo (Z = -5.874; P < 0.001) to 99 after 3 mo (Z = -5.865; P < 0.001) to 103 after 6 mo (Z = -6.063; P < 0.001). PSQI significantly decreased from 8 to 6 after 1 mo (Z = -3.922; P < 0.001), to 6 after 3 mo (Z = -4.329; P < 0.001) to 6 after 6 mo (Z = -4.410; P < 0.001).

Subjective Compliance

Data on self-reported continued use were obtained using the online questionnaires at three time points. After 1 mo of therapy,
subjective compliance (> 4 h per night, 7 days per week) was 91.8% (n = 110). After 3 mo of therapy 74.3% of the patients were self-reportedly compliant (n = 101) and after 6 mo the subjective compliance was 59.8% (n = 87). Subjective regular SPT use (> 4 h per night, 5 days per week) was 96.4%, after 3 mo and 89.1% and 74.4% after 6 mo.

Follow-up Cohort

Of the 106 patients, we chose to further analyze all patients for whom complete records could be collected. Questionnaire scores and percentage of supine sleep time of these 53 patients are shown in Table 5. Distribution of hours of SPT use is shown in Table 6. Median SPT use during 6 mo was 1,127 h [IQR = 191], or 6.7 h on average per night for all nights. Objective SPT compliance in this group of 53 patients (> 4 h per night, 7 days per week) was 100%.

DISCUSSION

This is the first long-term follow-up study to evaluate a large group of patients with POSAS sleeping with the SPT during a period of 6 mo. The main finding is that selected patients with mild to moderate POSAS can be effectively treated with the SPT, reducing the percentage of supine sleep time persistently over the course of 6 mo. In concordance with our previous study, sleeping with the SPT diminishes subjective sleepiness and improves sleep related quality of life in patients with mild to moderate POSAS (Table 4). The long-term decrease in median ESS from 11 (considered sleepy) to 8 (considered normal) in our group of patients with mild and moderate POSAS seems comparable to subjective sleep results using the ESS in patients with mild and moderate OSAS using CPAP (mean ESS decrease from 10 to 8 in 6 mo).27 Effectiveness of PT and of PT using the SPT in terms of AHI decrease for patients with POSAS have been demonstrated before.5,10 Figure 4 illustrates that the median percentage of supine sleep quickly decreases from 21% at baseline to approximately 6% at day 9 (end of training phase), that this percentage of supine sleep further decreases during the therapy phase (starting on day 10) to 2–3%, and that this percentage of supine sleep is maintained over time. This is an interesting finding because the most studied form of PT, the tennis ball technique, has been shown to be minimally effective in the long term, because more than 80% of long-term users either do not use it nor avoid the supine position while asleep during tennis ball therapy.17

Long-term follow-up is important in any study that evaluates treatment with a detachable device, because the device only exerts its effects when in use. CPAP devices currently are equipped with built-in counters to enable assessment of the hours of use. Several studies have shown that 29–83% of CPAP users are noncompliant with therapy (using study periods of 3 mo to 1 y), when compliance is defined as at least 4 h of CPAP use per night.19 Objective usage data for MAD, until recently, have been difficult to collect and limited to subjective self-report. However, recently it was shown that objective and subjective long-term MAD compliance data show a high correspondence.29 Long-term subjective MAD compliance rates vary greatly between studies and have shown to be within a range of 4% to 82% after 1 y of treatment.30–33 Long-term PT compliance has been hampered by discomfort and reports on compliance so far have been limited to subjective measurements. One study evaluated the tennis ball technique (TBT) and used a follow-up questionnaire in 67 patients for whom the TBT was prescribed, with an average follow-up time of 2.5 ± 1.0 y, and found that long-term compliance was less than 10%.17 Another group studied 14 patients with POSAS for whom a supine sleeping position preventive vest was prescribed, and found subjective compliance at an average time of 24 mo to be less than 30%.34 To our knowledge, only one study has been conducted evaluating objective long-term use of PT. In this study, 16 patients used a somewhat bulky mass placed against the back for a period of 3 mo. Using a built-in actigraphic device they found that their device, on average, was used during 73.7% ± 29.3% of nights for 8.0 ± 2.0 h/night.35 The SPT is equipped with a built-in sensor enabling assessment of hours of use by both physician and patient. Compliance, using CPAP’s compliance criteria,26 was 64.4% in our current study. Self-reported compliance after 6 mo of therapy seems to correspond well with the objective compliance rate and was 59.8%. Objective regular SPT use was 71.2%; subjective regular use was 74.4%. The high correspondence between subjective and objective compliance data is in line with a recent study focusing on subjective and objective MAD compliance data.29 This finding could suggest that patients are relatively accurate in their estimation and report of their mean use of more than 4 h per night. However, correlation between the self-reported and objective data on continuous use could not be calculated because of the differences in structure of the data. The subjective compliance rate was based on a single question at 1, 3, and 6 mo in which the mean use per night during the overall preceding period of use was questioned. The objective

Table 5—Questionnaire values and percentage of supine sleep time during 6 months of Sleep Position Trainer treatment (n = 53).

<table>
<thead>
<tr>
<th>Variable</th>
<th>Median</th>
<th>Median</th>
<th>Median</th>
<th>Median</th>
</tr>
</thead>
</table>

Values between brackets represent the interquartile range. ESS, Epworth Sleepiness Scale; FOSQ, Functional Outcomes of Sleep Questionnaire; PSQ, Pittsburgh Sleep Quality Index.

Table 6—Distribution of hours of Sleep Position Trainer use (n = 53).

<table>
<thead>
<tr>
<th>Hours of Use</th>
<th>n</th>
<th>% of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>0–249</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>250–499</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>500–749</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>750–999</td>
<td>13</td>
<td>25%</td>
</tr>
<tr>
<td>1,000–1,249</td>
<td>30</td>
<td>57%</td>
</tr>
<tr>
<td>1,250–1,509</td>
<td>10</td>
<td>19%</td>
</tr>
<tr>
<td>Total</td>
<td>53</td>
<td>100%</td>
</tr>
</tbody>
</table>

Long-Term Effectiveness, Compliance of SPT—van Maanen and de Vries

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data on continuous use were measured on a day-to-day basis by the SPT. In addition, increased patient guidance and the use of educational and positive reinforcement programs might be used to even further increase SPT compliance because these tools have been shown to increase CPAP compliance. To our knowledge, 64.4% is the second highest long-term compliance rate of any positional therapy device studied so far. Only the study by Heinzer et al. reported on a higher PT compliance rate. However, the shorter study period (3 versus 6 mo), the smaller sample size (n = 16 compared to n = 106) and strict inclusion criteria used in that study (prior nontolerance of either CPAP or oral device therapy and a required < 10% of total sleep time spent in supine sleeping position during a test night with the device) might overestimate their reported compliance rate.

There are some limitations concerning our study setup and data that need to be addressed. One hundred forty-five patients were included in our study. Thirty-nine patients did not register their SPT in the online database. No SPT use or SPT data could be retrieved in these patients, despite implementation of protocolled safety nets; registered patients would receive an email reminding them to fill out the questionnaires in case they had not done so in time. When designing this trial, the possibility of patients not registering online was not fully taken into account. SPT instructions and delivery were taken care of by a Dutch medical device distributor company. The process of registering online was left to the patient, which was not ideal from a research perspective in hindsight. However, the results of this study, in terms of follow-up potential, are likely a good reflection of clinical reality. Of these 106 patients, only 53 patients uploaded their SPT data for the full study period and filled in the questionnaires at two or more time points. Patients did not receive any other incentives to fill out the questionnaires or upload their data. The data retrieved over the full 6 mo might therefore have resulted in a positive selection bias, showing merely the best SPT users. However, some patients reportedly stopped using the SPT because they felt better, no longer had any subjective complaints, and learned to avoid sleeping in the supine position. We were not able to collect their experiences in the questionnaires because most of these patients had already stopped using the SPT in the first weeks of use and were therefore lost to follow-up. Any potential learning effect of PT in general or in sleeping with the SPT remains to be investigated.

This study lacks objective measures on treatment efficacy by means of a repeat PSG in all patients to evaluate effects on AHI, snoring. Although effects of SPT use on AHI have been reported before, effects of the SPT on snoring remain to be investigated. Another limitation of our study is the lack of a control group. Our results and conclusions could have been stronger and more valuable had we compared the SPT users to a group of patients with POSAS with another treatment regimen.

A final limitation of the current study was the lack of an educational program or positive reinforcement program for the patients. Loss to follow-up would probably have been less and compliance would probably have been higher given the positive results in trials with CPAP users.

It is our opinion that in patients with mild and moderate POSAS, PT could be the ideal method and maybe should be the initial treatment of POSAS. The treatment concept of SPT, which consists of a small apparatus that is able to register body position as well as provide active feedback effectively to its user during both night and day, seems to be the best currently available option for treating patients with POSAS. This cohort of patients with POSAS using the SPT for a 6-mo study period has shown that the SPT is capable of quickly reducing the percentage of supine sleep time within 10 days and maintaining this decreased percentage of supine sleep time over time. Furthermore, SPT use diminished subjective sleepiness and improved sleep-related quality of life. However, future prospective long-term research is necessary and should focus on objective PSG parameters in direct comparison with other generally accepted treatment modalities as well as objective measurements of continuous usage.

CONCLUSION
Over a period of 6 mo, sleeping with the SPT effectively and persistently decreases the percentage of supine sleep time, from 21% to 3% within 10 days and maintaining this 3% supine sleep time over 6 mo. The SPT significantly diminishes subjective sleepiness and improves sleep-related quality of life in patients with mild to moderate POSAS. Of the 106 patients studied, 64.4% using the SPT were considered compliant, defined as SPT use of more than 4 h per night during 7 days/w and 71.2% of patients used the SPT on a regular basis, defined as more than 4 h during 5 days/w. Subjective and objective compliance data corresponded well. Future research needs to focus on objective long-term treatment effects, particularly in relation to other already generally accepted POSAS treatment modalities.

ABBREVIATIONS
AHl, apnea hypopnea index
BMI, body mass index
ESS, Epworth Sleepiness Scale
FOSQ, Functional Outcomes of Sleep Questionnaire
OSAS, obstructive sleep apnea syndrome
POSAS, positional obstructive sleep apnea syndrome
PSQI, Pittsburgh Sleep Quality Index
PT, positional therapy
SPT, Sleep Position Trainer

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REFERENCES
Obstructive sleep apnea syndrome (OSAS) is a common disorder affecting at least 2% to 4% of the middle-aged population. It is characterized by recurrent episodes of complete or partial obstruction in the upper airway during sleep with consequences such as daytime somnolence, increased cardiovascular mortality, and traffic accidents. As measured by polysomnography (PSG), the severity of OSAS is expressed by the apnea-hypopnea index (AHI); AHI of 5–15/h indicates mild OSAS, 15–30/h is moderate, and an AHI ≥ 30 is severe. A supine sleeping position can influence OSAS severity and can be the only precipitating factor for OSAS. This so-called positional dependent OSAS (POSAS) is defined as a two-fold increase in AHI in supine compared to non-supine position and mostly with an AHI < 5 in non-supine position. Using this definition, Mador et al. observed that POSAS is very common in patients with OSAS and inversely related to the severity of OSAS: 49.5% in mild OSAS, 19.4% in moderate OSAS, and 6.5% in severe OSAS. In all patients, but especially in patients with mild OSAS, conservative measures such as weight reduction, alcohol and smoking abstinence, and optimization of nasal patency can diminish OSAS but seldom cure it. In patients with mild OSAS, continuous positive airway pressure (CPAP) compliance is poor. Mandibular reposition device (MRD) application is a highly effective therapy in mild and moderate OSAS or in CPAP failure, but health insurance reimbursement in most countries is still a problem; also 25% of the patients have a contraindication for MRD therapy because of dental and periodontal abnormalities. Due to difficulties
Positional therapy (PT) can be defined as preventing patients from sleeping in the supine sleeping position. Until recently positional therapy consisted of the so-called tennis ball technique (TBT). It consists of a bulky mass (tennis ball, bulge of hard foam, or inflated airbags) attached between the shoulder blades to prevent the patient from adopting a supine position during sleep.\(^5\)\(^{12}\)\(^{16}\)\(^{18}\) In mild POSAS patients, the normalization of the AHI with TBT is equivalent to CPAP during the overnight observation.\(^5\) Unfortunately, reported compliance with the TBT in the long term (≥ 6 months) is poor, varying from 6% to 29%, mainly due to discomfort and no improvement in sleep quality or daytime alertness.\(^13\)\(^{16}\)\(^{17}\) Therefore, there is a need for an effective positional therapy with better compliance. Recently, a new generation of PTs has been introduced: small, mainly indirect working devices, which give off a vibrating stimulus when sensing supine position. As the devices are more comfortable, it is predicted that compliance will be better.\(^18\)\(^{20}\)\(^{21}\) A recent study with the new sleep position trainer device (SPT) but without a control group showed indeed promising results.\(^18\) So the objectives of this randomized controlled study were to assess the efficacy and objectively measured daily compliance in patients with mild to moderate POSAS treated with the SPT or the TBT.

### Methods

#### Patients

Patients were eligible for this study if referred to the sleep medicine department in a large teaching hospital, based in the Netherlands because of suspected OSAS between January and August 2011. A thorough sleep history was taken, physical examination performed, and patients were screened with a portable home sleep-monitoring unit (PM). Patients were diagnosed with OSAS if they met the following criteria as defined by the American Academy of Sleep Medicine (AASM): complaints of excessive daytime sleepiness (naps during day/evening) or ≥ 2 of the following that were not better explained by other factors: choking or gasping during sleep, recurrent awakenings from sleep, refreshing sleep, daytime fatigue, and/or impaired concentration, in combination with an AHI ≥ 5.\(^21\) POSAS was defined as ≥ 2-fold AHI supine versus AHI non-supine, AHI < 10 in non-supine position, and sleeping in supine position between 10% and 90% of time. Patients in this study had to fulfill the POSAS and OSAS criteria twice (during screening and at baseline PSG). The maximum AHI was restricted to 30. Exclusion criteria were as follows: central sleep apnea syndrome, nasal obstruction or major facial or pharyngeal anatomic abnormalities likely to require surgery, night or rotating shift work, severe chronic heart failure, known history of a known cause of daytime sleepiness and severe sleep disruption (e.g. insomnia, periodic limb movement disorder, narcolepsy), seizure disorder, mental retardation, psychiatric disease, memory disorders. Consecutive POSAS patients with an AHI 5–30 received spoken and written study information and were invited for study participation by telephone call after at least one week.

#### Study Design

This was a prospective randomized study with 2 parallel groups of patients with POSAS, but otherwise non-selected successive patients. One group of patients received the SPT, the other the TBT. Randomized allocation of treatment took place after baseline PSG. The investigators seeing the patients and the patients themselves could not be blinded; however, randomization, PSG assessment, and data analyses were blinded. The study was approved by the Medical Ethical Committee of Medisch Spectrum Twente hospital (Enschede, Netherlands), Trial number: NL34934.044.10.

Patients participating in the study underwent a PSG and questionnaires at baseline and at the end of the study after 1 month (with PT). To objectively measure daily compliance in both study arms a SPT device in a non-vibrating but sensing mode was also built in the TBT equipment (see Appendix). The SPT accelerometer and thermometer data give absolute information whether and how long the therapy is used.\(^18\) Patients were instructed after randomization how to use their allocated PT modality and told to use the PT as soon and often as possible. Information that compliance was measured was not provided to the patients. Patients were seen at the outpatient clinic 2 weeks after starting therapy to check for problems and replace the batteries if needed.

#### Positional Treatment

The SPT (NightBalance, Delft, Netherlands) is a small lightweight device, placed in a pocket of a neoprene strap, attached around the patient’s chest.\(^18\) In this SPT a thermometer, accelerometer, microcomputer, battery and vibrating equipment and USB-connection are built-in. Data storage for ≥ 90 days is possible. After a sleep-in period of 30 minutes, when a patient remains in a supine position, a vibration will occur in a progressive manner from day 3 on. The idea is to gradually train patients in avoiding supine sleep position. During our study in 2011, we used the first generation SPT. The commercially online available Rematee band was used as control therapy. This is a TBT, the classical form of PT, whereby 3 inflated airbags are positioned on the back with an elastic band around the chest preventing directly supine position (see Appendix).

#### Measurements

#### Sleep Studies

At baseline and after one month a PSG was performed at home with the following in-hospital sensor placements: an electroencephalogram with F4-M1, C4-M1 derivations, nasal airflow (cannula), thoracic and abdominal respiratory movements with inductive plethysmography, chin EMG, vertical and horizontal eye movements, heart rate, and oximetry on the index finger. Sensor choice, settings, and scoring were performed according to the AASM 2007 rules.\(^22\) The alternative hypopnea 2007 definition (≥ 50% nasal flow amplitude drop with ≥ 3% O\(_2\) desaturation or arousal) was applied.\(^22\) Snoring was derived from the nasal flow sensor and expressed in the number of snores per total sleep time (TST) hour (snore index), periods of > 5 repetitive snores in TST (periodic snoring), and percentage of all snores occurring in supine position (snoring supine position percentage). Scoring was done by one technologist unaware of the type of PT the patient had worn.
The morning after baseline home PSG, using a preliminary automatic PSG report, the data were checked for data loss and to recheck the OSAS and POSAS inclusion criteria. Home PSG was performed with the Alice PDx (Philips-Respironics) and analyzed with BrainRT (OSG, Rumst, Belgium) software.

**Questionnaires and Scales**

The Epworth Sleepiness Scale (ESS) is an 8-point self-completed questionnaire assessment of the tendency to fall asleep during 8 various daytimes situations, with a score of 0 to 3 for each question. The Quebec Sleep Questionnaire (QSQ) is a validated OSAS-specific quality of life (QoL) questionnaire; 32 items are divided over 5 domains: sleepiness, diurnal symptoms, nocturnal symptoms, emotions and social interactions; each item is scored on a 7-point scale. The minimal clinical important difference (MCID) perceived by the patient before and during (CPAP) treatment is earlier described. A higher score means improvement. The QSQ was translated into Dutch by a forward- and back-translation process. Visual analogue scales [(VAS), range =50 to +50] were used to address change in snoring intensity, partner-perceived breathing stops, nighttime restlessness and movements, alertness and tiredness during daytime, and for perceived treatment effectiveness (last VAS with range 0–100). Preference of therapy had to be filled in to answer the question whether or not they would want to continue the therapy after the trial period. The ESS and QSQ were done twice; the VAS scores and the preference question only had to be filled in at the end of the study.

**Compliance**

All objectively measured daily compliance data were measured with the SPT device used in the SPT group but also in the TBT group (see study design) and expressed as: hours use per night, percentage of used days, everyday use, effective compliance, and adjusted compliance. Every day use was defined as use of PT for more than zero hours per day. Effective compliance was defined as > 4 h/day and > 5 of 7 days of the week use of PT. Two home PSGs, one without (baseline) and one with used PT (at end study) allowed us to calculate the individual TST. Adjusted compliance (%) was consequently calculated as (median) therapy use in hours per night use divided by the individual TST. In all except the adjusted compliance, dropouts were included in the analysis.

**Treatment Effectiveness**

Treatment effectiveness is presented in several ways: as treatment response defined as AHI reduction ≥ 50%, treatment success defined as AHI < 5, supine position reduction, and as supine-AHI reduction. Therapeutic efficacy can be defined as percentage improvement of the AHI between baseline and therapy. Mean disease alleviation (MDA) is than given by the product of therapeutic efficacy and adjusted compliance and expressed as percentage. This new measure makes different therapies in OSAS each with its own difference in compliance and effectiveness more comparable.

**Statistics**

Sample size calculation: positional therapy using the SPT was seen as equivalent to the TBT if the 95% confidence interval of the difference in percentage of total supine time was within ±5%. With an assumed reduction to 12%, standard deviation of 6%, α of 0.025, and power of 80%, we needed to include 22 patients within each group. Due to the high probability of skewed data that necessitates nonparametric testing, we aimed at 30 patients per group. Baseline characteristics are displayed as mean with standard deviation or median with range for continuous variables or as number with percentage for categorical variables. Differences between SPT and TBT in continuous variables were tested with a T-test or Mann-Whitney U test depending on the distribution. Differences in categorical variables were tested with χ² or Fisher exact tests as appropriate. Statistical analysis was performed using SPSS (version 15: SPSS Inc.; Chicago).

**RESULTS**

**Patients and Baseline Data**

Seventy-seven POSAS patients gave informed consent (Figure 1). Eight patients were directly excluded due to the study inclusion and exclusion criteria. Twenty-one patients declined participation in the study because as holiday plans, finding 2 extra PSGs too cumbersome, therapy preference, or no reason at all. Eighteen patients did not meet the POSAS criteria again with repeat baseline PSG, and 4 patients did not show up at the baseline PSG appointment. Of those 18 patients one patient, one day after randomization, when the preliminary PSG data were re-analyzed had to be excluded due to not meeting the POSAS AHI inclusion criteria at baseline; the patient was not started with his PT (TBT). With permission of the METC this patient was excluded. Hence, 55 patients were included. Twenty-six patients were assigned to using the TBT, and 29 patients to using the SPT. Due to 5 and 2 dropouts (see compliance and dropouts), 21 and 27 patients in, respectively, the TBT and SPT groups did have a PSG after one month of therapy.

![Figure 1](image-url)
Comparing baseline data between the 2 groups, 3 parameters were significantly different: sleep efficiency (p = 0.047), number of awakenings (p = 0.03), and a lower score for the QSQ-domain social interactions (p = 0.04). So the SPT group started with a lower sleep quality and a bit lower QoL.

Respiratory Data and Treatment Results

All patients used their therapies during the final home PSG night. Both therapies were equally effective in reducing supine position in TST, supine AHI, and snoring in supine position to a median of zero (Table 1); these 3 parameters when compared to baseline, showed a highly significant improvement without significant difference between the TBT and SPT groups (Table 1). A reflection of this is the 100% median snoring and supine position and supine AHI reduction (Table 2). A median of zero means that at least half the patients had at least a zero value, as illustrated in the AHI-supine during PT (Figure 2). Median AHI was significantly (both p = 0.02) reduced to 5.8 (0.2–23.1) and 3.9 (0.4–30.8), for, respectively, the TBT and SPT groups, without significant difference between the TBT and SPT groups (Table 1). The values for the snore index and periodic snoring indicated persistent snoring in the non-supine positions during therapy. Treatment response (AHI < 50%) was not different between the 2 groups. Treatment success, defined as AHI < 5, for the TBT and SPT was, respectively, 43% (9/21) and 68% (17/25); this numeric difference between TBT and SPT treatment response was, however, not statistically different (Table 2).

### Table 1—Characteristics, questionnaires, and polysomnography at baseline and 1 month.

<table>
<thead>
<tr>
<th></th>
<th>TBT Baseline</th>
<th>TBT 1-Month</th>
<th>SPT Baseline</th>
<th>SPT 1-Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number</td>
<td>26</td>
<td>21</td>
<td>29</td>
<td>27^</td>
</tr>
<tr>
<td>Male (%)</td>
<td>84.6</td>
<td>85.7</td>
<td>79.3</td>
<td>77.8</td>
</tr>
<tr>
<td>Age (years)</td>
<td>50.7 ± 12.2</td>
<td>50.1 ± 2.4</td>
<td>50.1 ± 10.6</td>
<td>50.4 ± 10.7</td>
</tr>
<tr>
<td>BMI (kg/m^2)</td>
<td>26.8 ± 3.0</td>
<td>27.1 ± 2.9</td>
<td>27.6 ± 4.5</td>
<td>27.3 ± 4.4</td>
</tr>
<tr>
<td>Epworth Sleepiness Scale score</td>
<td>7.3 ± 4.2</td>
<td>7.8 ± 4.3</td>
<td>6.4 ± 3.4</td>
<td>6.0 ± 3.6</td>
</tr>
<tr>
<td>QSO total score</td>
<td>4.7 ± 1.2</td>
<td>4.8 ± 1.3 *</td>
<td>4.7 ± 1.1</td>
<td>5.4 ± 1.2 **</td>
</tr>
<tr>
<td>QSO daytime sleepiness</td>
<td>4.9 ± 1.6</td>
<td>5.7 (2.2–6.9) *</td>
<td>5.1 ± 1.4</td>
<td>5.6 ± 1.5 *</td>
</tr>
<tr>
<td>QSO diurnal symptoms</td>
<td>3.8 ± 1.7</td>
<td>4.2 (1.2–6.5) *</td>
<td>4.0 ± 1.6</td>
<td>4.9 ± 1.5 **</td>
</tr>
<tr>
<td>QSO nocturnal symptoms</td>
<td>4.7 ± 1.1</td>
<td>4.8 ± 1.3</td>
<td>4.8 ± 1.0</td>
<td>5.5 ± 1.1 **</td>
</tr>
<tr>
<td>QSO emotions</td>
<td>5.6 ± 1.2</td>
<td>5.5 ± 1.3</td>
<td>5.3 ± 1.5</td>
<td>5.7 ± 1.5 *</td>
</tr>
<tr>
<td>QSO social interactions</td>
<td>5.8 ± 1.3</td>
<td>5.7 ± 1.0</td>
<td>4.9 ± 1.7 *</td>
<td>5.6 ± 1.1 *</td>
</tr>
<tr>
<td>Total sleep time (min)</td>
<td>366 ± 66</td>
<td>361 ± 55</td>
<td>367 ± 57</td>
<td>369 ± 57</td>
</tr>
<tr>
<td>Sleep latency NREM stage 1 (min)</td>
<td>7.9 (0.8–97.4)</td>
<td>9.9 (1.3–29.8)</td>
<td>11.4 (0.0–91.5)</td>
<td>14.2 (1.2–150.5)</td>
</tr>
<tr>
<td>WASO (min)</td>
<td>39.3 (21.0–98.5)</td>
<td>64.8 ± 36.5 *</td>
<td>50.0 (15.5–173)</td>
<td>47.8 ± 30.1</td>
</tr>
<tr>
<td>NREM stage 1 (% sleep period time)</td>
<td>2.1 (0.3–31.6)</td>
<td>3.3 (0.5–13.0)</td>
<td>4.7 (0.0–22.6)</td>
<td>3.8 (0.6–20.8)</td>
</tr>
<tr>
<td>NREM stage 2 (% sleep period time)</td>
<td>46.4 ± 10.9</td>
<td>41.7 (32.0–55.2)</td>
<td>42.9 ± 11.9</td>
<td>43.8 (32.8–59.3)</td>
</tr>
<tr>
<td>Sleep quality (%) b</td>
<td>42.0 ± 11.0</td>
<td>43.7 ± 9.1</td>
<td>43.0 ± 9.7</td>
<td>44.5 ± 9.1</td>
</tr>
<tr>
<td>Sleep efficiency (%)</td>
<td>87.6 (58.0–93.7)</td>
<td>81.3 ± 8.7</td>
<td>83.5 (63.7–92.2)</td>
<td>82.8 ± 9.8</td>
</tr>
<tr>
<td>Awakenings (n)</td>
<td>15.0 (4.0–8.0)</td>
<td>18.0 ± 9.2</td>
<td>19.0 (4.0–50.0)</td>
<td>13.8 ± 4.3 *</td>
</tr>
<tr>
<td>Arousal index</td>
<td>12.5 ± 6.2</td>
<td>9.6 (0.5–19.9)</td>
<td>10.8 ± 5.8</td>
<td>8.1 (3.8–33.3)</td>
</tr>
<tr>
<td>Awakening + Arousal Index</td>
<td>15.3 ± 6.6</td>
<td>13.2 (28.4–24.9)</td>
<td>14.0 ± 5.9</td>
<td>10.5 (5.6–37.5)</td>
</tr>
<tr>
<td>AHI</td>
<td>13.1 ± 9.1</td>
<td>5.8 (0.2–23.1) *</td>
<td>11.4 ± 4.9</td>
<td>3.9 (0.4–30.8) *</td>
</tr>
<tr>
<td>AHI supine</td>
<td>37.3 ± 24.0</td>
<td>0.0 (0.0–161) **</td>
<td>30.7 ± 15.3</td>
<td>0.0 (0.0–64.2) **</td>
</tr>
<tr>
<td>AHI non supine</td>
<td>3.3 (0.0–13.7)</td>
<td>5.0 (0.2–14.2)</td>
<td>3.9 (0.5–13.0)</td>
<td>3.6 (0.4–30.8)</td>
</tr>
<tr>
<td>RDI c</td>
<td>13.3 ± 9.1</td>
<td>6.0 (0.2–14.2) **</td>
<td>11.9 ± 4.6</td>
<td>3.9 (0.4–30.8) **</td>
</tr>
<tr>
<td>ODI (3%)</td>
<td>10.9 ± 7.7</td>
<td>5.4 (0.4–15.1) **</td>
<td>9.9 ± 5.0</td>
<td>4.4 (0.5–33.8) *</td>
</tr>
<tr>
<td>TST with SpO2 &lt; 90% (%)</td>
<td>3.5 (0.0–157.5)</td>
<td>0.2 (0.0–309.5)</td>
<td>4.5 (0.0–208.9)</td>
<td>1.7 (0.0–306.1)</td>
</tr>
<tr>
<td>Supine position (%)</td>
<td>31.1 (10.7–73.7)</td>
<td>0.0 (0.0–38.9) ***</td>
<td>27.9 (10.3–77.6)</td>
<td>0.0 (0.0–67.6) ***</td>
</tr>
<tr>
<td>Snore index d</td>
<td>375 (233.3–997)</td>
<td>316 (2.0–1275)</td>
<td>722 (28.6–1162)</td>
<td>764 (1–1322)</td>
</tr>
<tr>
<td>Periodic snoring a</td>
<td>36.6 (1.0–86.7)</td>
<td>26.7 (0.0–94.5)</td>
<td>67.3 (1.3–96.3)</td>
<td>64.3 (0.0–99.0)</td>
</tr>
<tr>
<td>Snoring supine position (%) f</td>
<td>41.0 (6.0–98.0)</td>
<td>0.0 (0.0–51.0) ***</td>
<td>26.5 (1.0–89.0)</td>
<td>0.0 (0.0–61.0) ***</td>
</tr>
</tbody>
</table>

Data expressed as mean ± standard deviation or median (min–max). * Difference at baseline TBT vs SPT p < 0.05. † Difference at 1-month TBT vs SPT, p < 0.05 (none). ‡ Difference baseline vs therapy for TBT or SPT p < 0.05. ** Difference baseline vs therapy for TBT or SPT p < 0.01. *** Difference baseline vs therapy for TBT or SPT p < 0.001. ± Respiratory data at 1-month are from 25 patients instead of 27 due to data loss (nasal flow and SpO2). NREM stage 3 + REM / sleep period time, expressed as percentage. AHI + RERAs. Number of all snores per total sleep time/hour. All periodic (> 5 repetitive snores) snoring episodes per total sleep time/hour. Percentage of all snores occurring in supine position. TBT, tennis ball technique; SPT, sleep position trainer; BMI, body mass index; QSO, Quebec Sleep Questionnaire; WASO, wake after sleep onset; REM, rapid eye movement sleep; n, number; AHI, apnea-hypopnea index; RDI, respiratory disturbance index; ODI, oxygen desaturation index; TST, total sleep time; SpO2, peripheral capillary oxygen saturation; NREM, non rapid eye movement sleep; RERA, respiratory-effort related arousal.
RCT with Sleep Position Trainer in Positional Sleep Apnea

Table 2—Respiratory data: comparing baseline to treatment.

<table>
<thead>
<tr>
<th></th>
<th>Tennis Ball Technique</th>
<th>Sleep Position Trainer</th>
<th>TBT vs SPT p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number</td>
<td>21</td>
<td>25</td>
<td>21 vs 25</td>
</tr>
<tr>
<td>Treatment response (AHI &lt; 50%)</td>
<td>13/21 (50.0)</td>
<td>16/25 (55.2)</td>
<td>0.701</td>
</tr>
<tr>
<td>Treatment success (AHI &lt; 5)</td>
<td>9/21 (42.9)</td>
<td>17/25 (68.0)</td>
<td>0.087</td>
</tr>
<tr>
<td>Supine position reduction (%)</td>
<td>100 (64.4–100)***</td>
<td>100 (97.2–100)***</td>
<td>0.197</td>
</tr>
<tr>
<td>Supine-AHI reduction (%)</td>
<td>100 (48.2–100)**</td>
<td>100 (100–100)**</td>
<td>0.261</td>
</tr>
</tbody>
</table>

Data expressed in number (%) or median percentage (interquartile range). ** p < 0.01. *** p < 0.001. TBT, tennis ball technique; SPT, sleep position trainer; AHI, apnea-hypopnea index.

Table 3—Sleep data, comparing baseline to treatment.

<table>
<thead>
<tr>
<th></th>
<th>Tennis Ball Technique</th>
<th>Sleep Position Trainer</th>
<th>TBT vs SPT p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number</td>
<td>21</td>
<td>27</td>
<td>21 vs 27</td>
</tr>
<tr>
<td>Total sleep time (min)</td>
<td>−19.9 ± 86.7</td>
<td>2.4 ± 58.7</td>
<td>0.294</td>
</tr>
<tr>
<td>Sleep efficiency (%) a</td>
<td>−3.5 ± 10.2</td>
<td>0.4 ± 9.1</td>
<td>0.172</td>
</tr>
<tr>
<td>Sleep quality (%) b</td>
<td>2.4 ± 11.1</td>
<td>2.1 ± 10.1</td>
<td>0.934</td>
</tr>
<tr>
<td>WASO (min)</td>
<td>23.0 ± 32.5*</td>
<td>−13.3 ± 39.0</td>
<td>0.001**</td>
</tr>
<tr>
<td>Awakenings</td>
<td>1.2 ± 9.5</td>
<td>−6.1 ± 8.2**</td>
<td>0.006**</td>
</tr>
<tr>
<td>Awakening + Arousal index</td>
<td>−2.7 ± 7.8</td>
<td>−1.9 ± 9.6</td>
<td>0.760</td>
</tr>
</tbody>
</table>

Data expressed as mean ± standard deviation. * p < 0.05. ** p < 0.01. a Total sleep time / time in bed. b NREM stage 3 + REM / sleep period time, expressed as percentage. TBT, tennis ball technique; SPT, sleep position trainer; WASO, wake after sleep onset; NREM, non rapid eye movement sleep; REM, rapid eye movement sleep.

Sleep Quality and Treatment Results

No differences between the TBT and SPT were noted in sleep parameters after one-month of therapy. However a tendency for less disturbed sleep was noted in the SPT treatment arm (Table 1). Compared to baseline, awakenings decreased −6.1 ± 8.2 (p < 0.001) only in the SPT group. WASO increased 23.0 ± 32.5 (p = 0.04) minutes in the TBT group and decreased 13.3 ± 39.0 (p < 0.001) minutes in the SPT group during therapy, indicating improved sleep quality in the SPT patients (Table 3).

Questionnaires, VAS, and Therapy Preference

After one month, no statistical differences in ESS, VAS, and in the 5 domains or total QSQ score were found between the 2 groups (Table 1). Compared to baseline, significant improvements were noted in all 5 QSQ-domains and total QSQ score in the SPT and in the domains daytime sleepiness, diurnal symptoms, and total QSQ score for the TBT group (Table 4). Comparing change from baseline in the TBT and SPT group a significantly higher improvement in QSQ total score (p = 0.03), domain nocturnal symptoms (p = 0.01), and the domain social interactions (p = 0.02) for the SPT patients was observed (Table 4). However the changes did not reach the “minimal clinically important difference” (MCID) as defined for CPAP therapy.24 All VAS scores improved, but without significant difference between the therapy groups. The question “Do you like to continue your therapy” was answered positive respectively in 10/21 (47.6 %) and 17/26 (65.4%) of the patients in the TBT and SPT group (Table 4). Patients using the SPT preferred their therapy more than patients using the TBT (p = 0.002).

Compliance and Dropouts

Effective compliance defined in line with the CPAP compliance definition (≥ 4 h/day + ≥ 5 days/week) was significant (p = 0.01) different between the 2 groups: 42.3% (11/26) for the
Highly significant different in favor of the SPT was every day and the percentage of days usage (both \( p = 0.005 \)). The median hours use per night and the number of dropouts were statistically not different between the 2 therapy groups. The intention to treat analysis included dropouts in all compliance data. Five dropouts in TBT and 2 in SPT were noted (\( p = 0.24 \)). Reasons for dropouts were shoulder/back pain (TBT), inability to turn on the back and (TBT/SPT) or vibrating noise (SPT). We measured daily compliance for both treatment arms. A negative trend for the compliance (≥ 4 h/night) is observed during one-month of use (Figure 3). At day 1, neither group started at 100% compliance for several reasons: not all patients started right away with their therapy, and therapy use ≥ 4 h is required.

Mean Disease Alleviation

TBT and SPT reduce the AHI (therapeutic efficacy), respectively, with 61.8% and 68.7%, with an adjusted compliance of 78.7% and 102.7% (\( p = 0.041 \)). A mean disease alleviation of 48.6% and 70.5% for, respectively, TBT and SPT was observed (\( p = 0.005 \); Table 6). Due to calculation of the average TST (baseline PSG + 1-month PSG expressed as mean), adjusted compliance can be higher than 100%.

Position Device Data

The reduction in supine sleep position starts on the first day with the TBT (direct prevention of supine position) and for the

### Table 4—Questionnaires and visual analogue scales, comparing baseline to treatment.

<table>
<thead>
<tr>
<th></th>
<th>Tennis Ball Technique</th>
<th>Sleep Position Trainer</th>
<th>TBT vs SPT p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>QSQ total score</td>
<td>0.3 ± 0.6 *</td>
<td>0.7 ± 0.6 **</td>
<td>0.033 *</td>
</tr>
<tr>
<td>QSQ daytime sleepiness</td>
<td>0.4 ± 0.7 *</td>
<td>0.5 ± 1.0 *</td>
<td>0.773</td>
</tr>
<tr>
<td>QSQ diurnal symptoms</td>
<td>0.5 ± 1.0 *</td>
<td>1.0 ± 1.1 **</td>
<td>0.068</td>
</tr>
<tr>
<td>QSQ nocturnal symptoms</td>
<td>0.1 ± 0.9</td>
<td>0.8 ± 0.8 **</td>
<td>0.009 **</td>
</tr>
<tr>
<td>QSO emotions</td>
<td>0.2 ± 0.6</td>
<td>0.4 ± 1.0 *</td>
<td>0.374</td>
</tr>
<tr>
<td>QSO social interactions</td>
<td>0.0 ± 1.1</td>
<td>0.8 ± 1.2 *</td>
<td>0.022 *</td>
</tr>
<tr>
<td>Epworth Sleepiness Scale</td>
<td>−0.0 ± 1.6</td>
<td>−0.6 ± 2.5</td>
<td>0.393</td>
</tr>
<tr>
<td>VAS snoring a</td>
<td>16.3 ± 18.1</td>
<td>20.5 ± 22.4</td>
<td>0.491</td>
</tr>
<tr>
<td>VAS breathing stops b</td>
<td>16.5 ± 17.7</td>
<td>15.9 ± 19.7</td>
<td>0.927</td>
</tr>
<tr>
<td>VAS nightly restlessness a</td>
<td>5.1 ± 20.8</td>
<td>12.3 ± 22.3</td>
<td>0.273</td>
</tr>
<tr>
<td>VAS alertness a</td>
<td>8.6 ± 24.1</td>
<td>12.1 ± 21.1</td>
<td>0.599</td>
</tr>
<tr>
<td>VAS tiredness a</td>
<td>9.0 ± 25.1</td>
<td>10.3 ± 21.0</td>
<td>0.847</td>
</tr>
<tr>
<td>VAS feeling pos.effect therapy b</td>
<td>55.2 ± 22.2</td>
<td>74.6 ± 19.0</td>
<td>0.002 **</td>
</tr>
<tr>
<td>Like to continue therapy? c</td>
<td>47.6</td>
<td>65.4</td>
<td>0.221</td>
</tr>
</tbody>
</table>

Data expressed as mean ± standard deviation or percentage. * \( p < 0.05 \). ** \( p < 0.01 \). a Range −50 to +50. b Range 0–100. c Question with answer Y/N as percentage (\( \chi^2 \) test). TBT, tennis ball technique; SPT, sleep position trainer; QSQ, Quebec Sleep Questionnaire; VAS, visual analogue scales.

### Table 5—Compliance.

<table>
<thead>
<tr>
<th></th>
<th>Tennis Ball Technique</th>
<th>Sleep Position Trainer</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number</td>
<td>26</td>
<td>29</td>
<td></td>
</tr>
<tr>
<td>Hours used per night</td>
<td>4.5 (1.1–7.0)</td>
<td>6.5 (5.5–7.2)</td>
<td>0.078</td>
</tr>
<tr>
<td>Percentage of days used a</td>
<td>77.2 (21.2–96.6)</td>
<td>100 (79.6–100)</td>
<td>0.005 **</td>
</tr>
<tr>
<td>Every day use b</td>
<td>4/26 (15.4)</td>
<td>15/29 (51.7)</td>
<td>0.005 **</td>
</tr>
<tr>
<td>Effective compliance (%) c</td>
<td>11/26 (42.3)</td>
<td>22/29 (75.9)</td>
<td>0.011 *</td>
</tr>
</tbody>
</table>

Data derived from daily measurements and expressed as median (interquartile range) or number (%). Dropouts included in all calculations. * \( p < 0.05 \). ** \( p < 0.01 \). a Percentage of days use of TBT/SPT (≥ 0 h). b Every day use of TBT/SPT (≥ 0 h). c Use TBT or SPT ≥ 4 h/night + ≥ 5 days/week. TBT, tennis ball technique; SPT, sleep position trainer.
SPT from day 3 (first 2 days only sensing). This resulted in supine sleep time position drop from 25% to < 5% from day 5 on for the SPT and between 4% and 10% for the TBT during the entire month (Figure 4). The time in bed for those who used the device was identical: 6.58 and 6.56 h, respectively, for TBT and SPT. Only in the SPT group the vibration episodes and reactions (turning to a non-supine position) of the patients where available (Figure 5). The vibration episodes (mean of 5.3) in this first generation SPT were not always followed by a turning reaction (mean 3.6).

DISCUSSION

The present study demonstrates more than 30% effective compliance difference between the two study arms, in favor of the SPT group. Both therapies equally minimize supine sleep position, supine-AHI, and supine snoring, and reduce AHI to almost normal (AHI < 5) values when PT is used. The SPT was used every day in 51.7% of the patients, whereas the TBT was used every day in 15.4% of the patients. The observed high effective compliance of 75.9% after a month of SPT use in mild (symptomatic, but mean ESS < 10) OSAS patients where therapy adherence due to mild disease severity is known to be poor is striking. Patient dropouts (2 SPT; 5 TBT) due to discomfort of PT in both therapies were included in this analysis, so the compliance in users is higher. Compliance did decline with time, but the gap (Figure 3) between both therapies was wider at the end of the study, suggesting a progressive difference in compliance between both therapies. One can postulate that a cumbersome therapy as the TBT or a vibrating device as the SPT could influence sleep quality. All sleep treatment results pointed to a small improvement in sleep quality in the SPT group and a minor decrease in the TBT group, with significant differences in treatment effect between the two groups in favor of the SPT group for WASO and awakenings.

The QSQ showed significant but modest treatment effects, and the changes did not reach the values for the MCID as described in the original article of the QSQ.24 This questionnaire was developed in OSAS patients with an AHI of 29 and ESS of 14 with response measurement with and without CPAP.24 It can be argued that the MCID described is too restrictive for therapy evaluation in mild OSAS.

Comparing treatment effects after one month of therapy showed significant differences in favor of the SPT for QSQ total score and two QSQ domains. The VAS for “Feeling positive effect of PT therapy” was also in favor of the SPT. As expected during therapy, we observed almost no snoring in supine position. Compared to baseline, overall snoring (snore index and periodic snoring) still remained high, due to persistent snoring in non-supine position. Snoring in non-supine position is

---

### Table 6—Mean disease alleviation.

<table>
<thead>
<tr>
<th></th>
<th>Tennis Ball Technique</th>
<th>Sleep Position Trainer</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number</td>
<td>21</td>
<td>25</td>
<td></td>
</tr>
<tr>
<td>Therapeutic efficacy (%)</td>
<td>61.8 (4.6–72.4)</td>
<td>68.7 (19.7–78.8)</td>
<td>0.349</td>
</tr>
<tr>
<td>Adjusted compliance TST (%)</td>
<td>78.7 (12.7–105.9)</td>
<td>102.7 (84.6–114.7)</td>
<td>0.041 *</td>
</tr>
<tr>
<td>Mean disease alleviation TST (%)</td>
<td>48.6 (7.9–65.4)</td>
<td>70.5 (58.1–78.8)</td>
<td>0.005 **</td>
</tr>
</tbody>
</table>

Data expressed as median (interquartile range). * p < 0.05. ** p < 0.01. *Baseline minus endpoint apnea-hypopnea index expressed as percentage of baseline. †Hours/day use as percentage of polysomnography derived TST. ‡Product of adjusted compliance and therapeutic efficacy divided by 100. TST, total sleep time.
probably less loud than snoring in supine position; however, we did not measure decibels.

To really compare different OSAS therapies, MDA can be used. MDA is a proposed new treatment measure; it is the product of the therapeutic efficacy (ability of a treatment to reduce the AHI) and the adjusted compliance (objectively measured compliance over a certain period with individual TST taken into account). For MRD and CPAP, MDA of 50% has been published. We found a high MDA of 70.5% for the SPT and a significantly lower MDA of 48.6% for the TBT. The high MDA of the SPT is the result of a good therapeutic efficacy and very high-adjusted compliance. The reported lower MDA for CPAP is a reflection of lower adjusted compliance. Looking at the daily SPT performance in the SPT group, we noted that supine position was effectively prevented; remarkably, not all vibration episodes were followed by a movement to a non-supine position. The manufacturer of the SPT commented that after 30 seconds, the vibration was programmed to stop, and that this has been adapted in newer SPT generations.

Limitations of our study are as follows. Firstly, at baseline, three parameters where significantly worse in the SPT group: QoSQ-domain social interactions sleep efficiency and number of awakenings (Table 1). So the SPT group started with less QoL for one of the five QSQ domains and less sleep quality in two of the twelve sleep parameters. These baseline differences between the two groups might have occurred by chance. Secondly, as expected, both therapies were effective in preventing supine position and therefore POSAS as long as the PT was used— as was the case during PSG at one month. However, between baseline and one month, the large compliance difference between therapies did not translate into a statistical difference in ESS. One explanation is that our groups were too small to find a statistical difference. Another explanation is perhaps the fact that we had a very mild POSAS group with daily complaints but normal ESS at inclusion; room for improvement is then limited. Still, 75.9% of the SPT group used their therapy more than 4 hours/day and at least 5 days a week during one month; and sleep quality, QoQ, and AH1 were also significantly improved. Thirdly the MDA we found is very high; this figure can decline when longer-term compliance results with the SPT are evaluated. One study evaluating the effect of SPT has recently been published; in 36 POSAS patients, the median AH1 decreased from 16.4 to 5.2. These patients were sleepy than in our study with an ESS of 11. A significant decrease in ESS and Functional Outcome of Sleep Questionnaire and a high compliance (without dropouts) at one month of 92.7% were observed. Finally, the economic aspects of these two therapies were not studied.

In mild OSAS patients the prevalence of POSAS is approximately 50%, suggesting that there is a huge potential for PT. There is not much doubt anymore that PT can be an effective therapy. New positional devices seem to be capable of improving short-time compliance as has been shown in other studies and in our randomized study. The main issue is whether the reported poor long-term compliance of the older TBT can be indeed improved with the new PTs using these small ergonomic vibrating devices. Thus, long-term compliance studies are now really needed.

In conclusion, in mild positional depended OSAS the new SPT device and the standard TBT are equally effective. Compared to standard PT with the TBT, compliance, mean disease alleviation, sleep quality, and quality of life are significantly improved with the SPT.

REFERENCES


SUBMISSION & CORRESPONDENCE INFORMATION

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DISCLOSURE STATEMENT

The study was self-funded; the investigators and authors received no financial support in order to avoid interference and pressure from third parties. Sleep studies were performed as usual care (portable monitoring type III selection, PSGs). The TBT (Rematee band) was bought on the commercial market. The SPTs (sleep position trainers) were provided by the producing company NightBalance. NightBalance provided also the sleep position trainers used in a non-vibrating, but sensing mode for daily compliance measurement in the TBT group. In the contract with NightBalance it was explicitly stated that NightBalance had no influence on the publication, no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript. Based on this agreement the start of the study was approved by the Medical Ethics Committee Twente, The Netherlands. There was no off-label or investigational use. The authors have indicated no financial conflicts of interest. The study was performed at Medisch Spectrum Twente Hospital, Pulmonary and Sleep department, Haaksbergenstraat 55, 7513 ER, Enschede, The Netherlands.

APPENDIX

Figure S1—Equipment used in study.

left: Rematee® (tennis ball technique) with extra pocket for sleep position trainer (in non-vibrating mode) to measure daily compliance. middle: 0–10 cm scale. right: normal sleep position trainer.

Figure S2—Example of equipment position.

An example of a person with the two studied forms of position therapy in place. The tennis ball technique (Rematee®, with 3 airbags on the subject’s back), and sleep position trainer (secured with strap and pocket on the front of the subject) are shown.
A promising concept of combination therapy for positional obstructive sleep apnea

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Original Article

Purpose The objective of this randomized controlled trial was to assess the additional effect of a chest-worn sleep position trainer (SPT) in patients with residual supine-dependent obstructive sleep apnea (sdOSA) under mandibular advancement device (MAD) therapy.

Methods Baseline and follow-up polysomnography with MAD were performed. Twenty patients with sdOSA under MAD therapy underwent two consecutive randomized polysomnographies: one with SPT and one with combination of SPT + MAD. Data are presented as median (quartile 1, quartile 3).

Results The SPT reduced the time spent in supine sleeping position compared to baseline and MAD therapy. Both MAD and SPT were individually effective in reducing the overall apnea/hypopnea index (AHI) significantly when compared to baseline from 20.8 (15.1; 33.6)/h at baseline to 11.0 (6.7; 13.8)/h and to 11.1 (3.5; 17.7)/h with MAD or SPT, respectively. The combination of SPT + MAD further reduced the overall AHI to 5.7 (3.6; 7.4), which was significantly lower than with MAD alone (p<0.001) and SPT alone (p<0.008), respectively.

Conclusions The results of this study indicate that combination of SPT + MAD leads to a higher therapeutic efficacy in patients with sdOSA under MAD therapy when compared to one of the treatment modalities alone.

Keywords Obstructive sleep apnea/hypopnea syndrome · Sleep-disordered breathing · Supine-dependent

Introduction

Approximately 50–60 % of patients with obstructive sleep apnea (OSA) suffer from supine-dependent OSA (sdOSA) defined according to Cartwright [1] as having twice as many respiratory events in the supine sleeping position compared to the non-supine sleeping position. Mador et al. [2] defined sdOSA as having twice as many respiratory events in the supine position than in non-supine positions along with an apnea/hypopnea index (AHI) <5 events/h in the non-supine position and a 15-min threshold for sleep in supine and non-supine position. A third definition of sdOSA was introduced...
by Marklund et al. [3, 4] defined as a supine AHI ≥10 events/h together with a non-supine AHI of <10 events/h.

Positional therapy is a treatment modality aimed at preventing sleep in the supine position [5]. It is recently shown during drug-induced sleep endoscopy (DISE) that a change of body position from supine to lateral position leads to improvement of upper airway collapse in patients with sdOSA [6]. In the future, DISE could be performed in both the supine and lateral positions [7]. The most widely used technique to avoid the supine sleeping position involves strapping a bulky object to the back of the patient thereby preventing supine positioning. Several studies have shown that such therapies have a significant positive effect on snoring and OSA severity in patients with sdOSA [5, 8–12]. However, the bulky object is uncomfortable for patients and results in disturbed sleep and low long-term compliance rates [8, 9]. Therefore, positional therapy has not found its way into daily OSA treatment routine to date [13]. In order to overcome such compliance problems, both a new neck-worn device and a chest-worn device correcting the supine sleeping position by activating a vibration alarm were evaluated. This novel concept of positional therapy showed promising results in reducing apnea severity, together with a higher compliance [14, 15].

Oral appliance therapy is a non-invasive treatment for patients with snoring and OSA [16]. The most common type of oral appliances prescribed for the treatment of OSA is the mandibular advancement device (MAD) worn intraorally at night in order to reduce upper airway collapse by protruding the mandible [4, 17–19]. This treatment modality, although not as effective as continuous positive airway pressure (CPAP) in reducing apnea severity, is preferred by the majority of patients and has a relatively high objective compliance rate [20–22].

In a recent study, it was found that up to 34 % of patients treated with MAD therapy showed sdOSA under MAD therapy [23]. Our research hypothesis is that those patients could benefit from additional positional therapy.

The aim of this prospective randomized controlled trial (RCT) was to investigate the feasibility of the additional use of a chest-worn sleep position trainer (SPT) in patients with sdOSA under MAD therapy.

Material and methods

Participants, setting, and study design

In Belgium, CPAP is the standard treatment for patients with moderate to severe OSA (AHI ≥20 events/h) and is fully reimbursed in these patients. Therefore, our policy is to propose a trial of CPAP therapy to any patient with an AHI of at least 20 events/h. In our multidisciplinary setting, patients with mild OSA (AHI <20 events/h) and patients with CPAP intolerance are referred to the multidisciplinary dental sleep clinic involved in the decision-making for the implementation of MAD therapy [24].

Twenty patients with a residual sdOSA (AHI ≥5/h) following both Cartwright’s [5] and Marklund’s [3, 4] criteria under MAD therapy were randomly selected out of our patient population. At the start of MAD therapy, patients were not judged suitable for MAD treatment if they suffered from any pre-existing active temporomandibular joint dysfunction, if their dental status or periodontal health precluded them from wearing an oral appliance, or if they were fully edentulous [25, 26]. In addition, patients with other sleep disturbances than sleep-related breathing disorders were excluded from the study.

The patients were invited to participate in this RCT design in which two treatment modalities were tested in a randomized order: the SPT and combination of SPT + MAD therapy. The other inclusion criteria were ≥20 % of total sleep time spent in the supine position during polysomnography (PSG) with MAD and unchanged body mass index (BMI±1 kg/m²) between diagnostic PSG and inclusion in the study.

Seven patients had a baseline AHI <20 events/h and were therefore CPAP naive. CPAP therapy was offered in the other 13 patients: 10 of them could not tolerate the CPAP device, two patients refused to start CPAP therapy, and one patient wanted an alternative for CPAP. The study design included a baseline level I PSG and a follow-up PSG with the MAD in situ. These PSGs were performed in routine clinical practice to assess the therapeutic efficacy of the MAD.

Patients were randomly allocated in a 1:1 ratio to be treated with either the SPT prior to combination therapy or combination therapy prior to the SPT, see Fig. 1. At the end of the study, but before knowing the results of the consecutive study nights during the RCT, patients were asked to fill out a questionnaire about their personal therapy preference (MAD, SPT, or combination of SPT + MAD).

The reported trial was conducted in accordance with the institutional guidelines of the ethical committee (Belgian registration number: B300201212947) and informed consent was obtained. The trial was registered at clinicaltrials.gov (NCT01535521).

Oral appliance

Patients were treated with a custom-made, titratable MAD (Respident Butterfly, Dormoco, Nijlen, Belgium (n=14) or SomnoDent Flex, Somnomed AG, Australia (n=6)). After receiving full explanation of the titration procedure, patients were instructed to gradually titrate the MAD until subjective
resolution of symptoms occurred or until the maximum comfortable limit was reached.

Sleep position trainer

A chest-worn SPT placed at the level of the sternum was used in this study (NightBalance™, Delft, The Netherlands) (Fig. 2) [14]. The SPT is a small, lightweight device (72 × 35 × 10 mm, 25 g) that allows for body position changes during sleep without any movement restrictions. The device continuously monitors position, providing a vibration stimulus when in supine position. The vibration is variable in frequency and gradually increases in amplitude and duration until the patient shifts to a non-supine position (Fig. 2).

Polysomnographic outcome measures

One individual who was blinded for the treatment assignment scored the polysomnographic evaluations. The severity of OSA was expressed by the overall AHI, defined as the average number of apneas and hypopneas per hour of sleep occurring in the supine and non-supine position, respectively. The positional change index was defined as the total number of positional changes during sleep per hour of total sleep time [27]. Treatment response was defined as a reduction in overall AHI under therapy of ≥50 % compared to baseline. Another success criterion used in this study was a reduction in overall AHI of ≥50 % compared to baseline combined with a post-treatment AHI of <5 events/h.

Statistical analysis

Data were statistically analyzed using SPSS software (SPSS version 21, Statistical Package for Social Sciences, SPSS Inc., Chicago, Illinois, USA). A power calculation revealed that with 20 patients, a power of 80 % with an effect size of 0.7 could be achieved at a significance level of 5 %.

The nonparametric Wilcoxon-signed rank test for paired observations was performed to compare different variables among the different study nights. Bonferroni correction for multiple comparisons was performed when comparing the results of the four different study nights. The significance
level was set at $p<0.05$, and the corrected significance level was $p<0.008$. The McNemar test was performed to compare the success rates of the different study nights. Since the data were not normally distributed, data are expressed as median values and their lower and upper quartiles (Q1, Q3).

Results

Subjects

Twenty patients with sdOSA under MAD therapy (age, 52±11 years; male/female, 11/8; overall AHI, 24.6±10.2/h; body mass index (BMI), 26.4±3.0 kg/m$^2$) were included in this RCT, see Table 1 for the baseline characteristics. There was no significant difference in age, weight, or sleep apnea severity between the two randomized groups. Four patients (21 %) were non-supine-dependent at baseline according to Cartwright’s definition, but all of them became supine-dependent under MAD therapy.

There was one patient who suffered from non-apneic snoring at baseline and was excluded from further analysis.

Time spent in supine sleeping position

Figure 3 shows the percentages of total sleep time spent in supine position during the four study nights: baseline, with MAD, with SPT, and with combination of SPT + MAD therapy. The SPT was found to be effective in reducing the time spent in supine position compared to baseline from 31.9 (15.4; 52.4)% at baseline to 0.0 (0.0; 1.1)% with SPT ($p=0.001$).

In addition, the time spent in supine position was reduced with the SPT compared to MAD therapy, from 49.5 (32.6; 48.9)% with MAD to 0.0 (0.0; 1.1)% with SPT ($p<0.001$), respectively. The time spent in the supine position with SPT + MAD therapy was 0.0 (0.0; 1.0)% and was significantly lower compared to baseline ($p=0.001$) or MAD therapy alone ($p<0.001$).

Positional change index

The frequency of positional changes was similar between the different study nights. The positional change index at baseline was 2.0 (1.6; 2.8)/h, which was not significantly different from the positional change index during MAD therapy [1.7 (1.2; 2.4)/h], SPT therapy [2.2 (1.6; 3.0)/h], or combination therapy [2.4 (1.7; 3.4)/h].

Polysomnographic efficacy

The polysomnographic results of respiratory disturbances and sleep quality for the different study nights are shown in Table 2.

Respiratory disturbances

There was a significant difference in overall AHI between the four conditions tested, as graphically illustrated in Fig. 4. Both MAD and SPT were individually effective in reducing the median overall AHI significantly when compared to baseline, from 20.9 (17.0; 34.0)/h to 11.0 (6.6; 14.0)/h and to 21.8 (3.9; 17.9)/h, respectively. Combination SPT + MAD therapy further reduced the median overall AHI to 5.5 (3.4; 7.2)/h. This was significantly lower when compared to baseline ($p<0.001$), MAD alone ($p<0.001$) and SPT alone ($p<0.008$).

The supine AHI was reduced effectively with MAD when compared to baseline, from 39.1 (26.4; 58.2)/h to 21.8 (14.8; 29.5)/h. In addition, the SPT further reduced the supine AHI significantly when compared to MAD therapy to a supine AHI of 0.0 (0.0; 11.5)/h.

In contrast to the SPT, MAD therapy was effective in reducing the non-supine AHI values when compared to baseline. Moreover, the non-supine AHI values with combination SPT + MAD therapy were significantly lower when compared to both baseline and SPT and comparable to that of the MAD alone.

Table 1 Baseline characteristics of the study population

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Mean±SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>52.5±10.5</td>
</tr>
<tr>
<td>Gender</td>
<td>57.9 % male</td>
</tr>
<tr>
<td>Body mass index, BMI (kg/m$^2$)</td>
<td>26.4±3.0</td>
</tr>
<tr>
<td>Overall apnea/hypopnea index, AHI (events/h)</td>
<td>20.9 (17.0; 34.0)</td>
</tr>
<tr>
<td>Supine AHI (events/h)</td>
<td>39.1 (26.4; 58.2)</td>
</tr>
<tr>
<td>Non-supine AHI (events/h)</td>
<td>11.1 (6.3; 26.1)</td>
</tr>
</tbody>
</table>

Data are expressed as mean±standard deviation (SD), percentages or median (Q1; Q3)
Sleep quality

Total sleep time, sleep efficiency, and percentage of stage 1, stage 2, and REM sleep did not differ significantly between the different study nights (Table 2). There was a significant increase in stage 3 sleep with MAD compared to baseline. The arousal index increased significantly with SPT when compared to MAD therapy \((p<0.008)\) and combination SPT + MAD therapy \((p<0.008)\) but not when compared to baseline. However, there was a decrease in the percentage of arousals associated with respiratory events during PSGs with MAD alone, SPT alone, and combination SPT + MAD therapy from 35.4 (24.8; 59.4)\% at baseline to 17.1 (7.0; 32.0)\%, 19.6 (4.7; 32.3)\%, and 8.9 (2.9; 12.9)\%, respectively. The percentage of arousals associated with respiratory events was the lowest during combination SPT + MAD therapy.

### Table 2: Polysomnographic results of the different study nights

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Baseline</th>
<th>With MAD</th>
<th>With SPT</th>
<th>With SPT + MAD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall AHI (events/h)</td>
<td>20.9 (17.0; 34.0)</td>
<td>11.0 (6.6; 14.0)*</td>
<td>12.8 (3.9; 17.9)*</td>
<td>5.5 (3.4; 7.2)<em>,</em></td>
</tr>
<tr>
<td>Supine AHI (events/h)</td>
<td>39.1 (26.4; 58.2)</td>
<td>21.8 (14.8; 29.5)*</td>
<td>0.0 (0.0; 11.5)<em>,</em></td>
<td>0.0 (0.0; 22.7)*</td>
</tr>
<tr>
<td>Non-supine AHI (events/h)</td>
<td>11.1 (6.3; 26.1)</td>
<td>3.9 (2.0; 5.0)*</td>
<td>12.8 (3.8; 17.2)*</td>
<td>4.8 (2.0; 6.0)<em>,</em></td>
</tr>
<tr>
<td>ODI (events/h)</td>
<td>7.7 (6.6; 16.5)</td>
<td>3.8 (1.2; 5.5)*</td>
<td>2.6 (1.0; 4.6)*</td>
<td>1.8 (1.0; 3.0)<em>,</em></td>
</tr>
<tr>
<td>Mean SaO2 (%)</td>
<td>94.9 (93.6; 95.8)</td>
<td>94.8 (93.8; 96.2)</td>
<td>95.3 (94.0; 96.2)</td>
<td>95.4 (94.1; 96.9)</td>
</tr>
<tr>
<td>Min SaO2 (%)</td>
<td>84.7 (79.0; 86.0)</td>
<td>87.0 (84.0; 91.0)</td>
<td>88.0 (84.0; 90.0)*</td>
<td>89.0 (87.0; 91.0)*</td>
</tr>
<tr>
<td>TST (min)</td>
<td>394.5 (361.2; 420.6)</td>
<td>419.0 (407.0; 452.5)</td>
<td>405.5 (386.5; 438.2)</td>
<td>413.0 (385.0; 444.2)</td>
</tr>
<tr>
<td>Sleep efficiency (%)</td>
<td>85.1 (79.4; 87.2)</td>
<td>87.5 (82.4; 92.6)</td>
<td>84.6 (80.6; 87.9)</td>
<td>84.2 (79.0; 89.7)</td>
</tr>
<tr>
<td>Stage N1 (% TST)</td>
<td>5.8 (3.4; 6.7)</td>
<td>3.9 (3.2; 5.6)</td>
<td>4.4 (3.3; 6.2)</td>
<td>4.1 (3.1; 4.9)</td>
</tr>
<tr>
<td>Stage N2 (% TST)</td>
<td>51.4 (38.7; 54.6)</td>
<td>47.9 (43.5; 51.0)</td>
<td>48.7 (48.0; 51.2)</td>
<td>46.6 (39.0; 50.2)</td>
</tr>
<tr>
<td>Stage N3 (% TST)</td>
<td>11.9 (5.9; 18.9)</td>
<td>20.0 (15.3; 22.8)*</td>
<td>15.2 (12.3; 18.9)</td>
<td>17.6 (11.4; 22.7)</td>
</tr>
<tr>
<td>Stage REM (% TST)</td>
<td>17.3 (13.7; 21.3)</td>
<td>21.2 (15.3; 26.2)</td>
<td>20.5 (15.6; 26.1)</td>
<td>20.5 (19.1; 27.7)</td>
</tr>
<tr>
<td>Arousal index (events/h)</td>
<td>10.1 (6.6; 15.0)</td>
<td>9.2 (7.3; 14.7)</td>
<td>19.5 (11.2; 24.3)*</td>
<td>11.7 (6.7; 13.6)<em>,</em></td>
</tr>
<tr>
<td>Percentage of respiratory arousals (%)</td>
<td>35.4 (24.8; 59.4)</td>
<td>17.1 (7.0; 32.0)*</td>
<td>19.6 (4.7; 32.3)*</td>
<td>8.0 (2.9; 12.9)<em>,</em></td>
</tr>
<tr>
<td>Number of awakenings</td>
<td>22.0 (13.0; 29.0)</td>
<td>17.0 (13.3; 21.5)</td>
<td>21.5 (14.5; 30.0)</td>
<td>18.0 (13.3; 24.8)</td>
</tr>
<tr>
<td>Percentage of TST in supine position (%)</td>
<td>31.9 (15.4; 52.4)</td>
<td>49.5 (32.6; 48.9)</td>
<td>0.0 (0.0; 1.1)<em>,</em></td>
<td>0.0 (0.0; 1.0)<em>,</em></td>
</tr>
<tr>
<td>Positional change index (changes/h)</td>
<td>2.0 (1.6; 2.8)</td>
<td>1.7 (1.2; 2.4)</td>
<td>2.2 (1.6; 3.0)</td>
<td>2.4 (1.7; 3.4)</td>
</tr>
</tbody>
</table>

Data are presented as median (Q1, Q3)

AHI = apnea/hypopnea index, ODI = oxygen desaturation index, TST = total sleep time, REM = rapid eye movement

*Statistically significant \((p<0.008)\) as compared to baseline

$Statistically significant \((p<0.008)\) as compared to PSG with MAD

∞Statistically significant \((p<0.008)\) as compared to PSG with SPT

**Sleep quality**

Fig. 4 Overall apnea/hypopnea index (AHI) for the different conditions tested. The different gray scales represent the varying levels of sleep apnea severity, ranging from normal nocturnal breathing (AHI <5/h sleep), mild OSA (AHI 5–15/h), moderate OSA (AHI 15–30/h), to severe OSA (AHI >30/h). Left panel: Box plots for the four different study nights. The 75th and 25th percentiles are represented by the upper and lower margins, the mean values by the closed dots, and the median values by the horizontal line. Whiskers represent the maximum value (top) and the minimum value (bottom) of the dataset. Outliers are represented by an open dot. Right panel: The individual patient data for the different study nights are plotted in line graphs.
Treatment outcome

Overall, treatment response rate (≥50 % reduction in overall AHI when compared to baseline) was significantly higher with combination of SPT + MAD (95 %) when compared to MAD alone (45 %; \( p < 0.01 \)) or SPT alone (55 %; \( p < 0.01 \)). While using success defined as a reduction in overall AHI of ≥50 % compared to baseline combined with a post-treatment AHI of <5 events/h, the success rates were 0, 25, and 35 %, respectively for MAD alone, SPT alone, or combination of SPT + MAD.

Subjective preference of therapy

Fifteen patients filled out the subjective questionnaire. Four patients identified MAD therapy as their subjective treatment of choice, four patients preferred SPT, and seven patients preferred the combination of SPT + MAD.

Discussion

This prospective RCT was the first to evaluate the feasibility and the efficacy of an additional chest-worn SPT in patients who were unsuccessfully treated with MAD therapy due to the presence of sdOSA under MAD therapy. The results indicate that the SPT used in this study significantly reduced the time spent in the supine position when compared to baseline or MAD therapy. Furthermore, both MAD and SPT were individually effective in reducing the apnea severity in patients with sdOSA under MAD therapy. In addition, combination SPT + MAD therapy leads to a higher therapeutic efficacy in patients with sdOSA under MAD therapy when compared to one of the treatment modalities alone.

It is reported in literature that a treatment modality for OSA that is not able to completely eliminate all breathing abnormalities leaves the patient with a residual OSA although often less severe than the initial OSA. Therefore, the residual OSA is probably more supine-dependent since supine-dependent OSA is more frequently seen in mild OSA. In a previous study, it was described that one third of patients under MAD therapy have a residual sdOSA. It was hypothesized that these patients with residual sdOSA under MAD therapy could benefit from additive therapy with SPT.

Most of the included patients (80 %) were also supine-dependent at baseline. In those patients, monotherapy with SPT should be considered as a first treatment option. However, in the past, most of the positional therapies had low acceptance and compliance due to the bulkiness of the devices and, therefore, was not frequently prescribed as a therapeutic option. Recently, the technology of positional therapy has been improved, with promising results. Additionally, our results showed that the success rate of SPT alone was up to 55 %. The most promising results were achieved with combination SPT + MAD therapy, with success rates up to 95 %.

In the present study, 95 % of patients were responders to combination SPT + MAD therapy based on success criteria defined as a reduction in overall AHI of ≥50 % according to literature [28]. MAD therapy was effective in reducing both supine AHI and non-supine AHI when compared to baseline (Table 2). This indicates that MAD therapy, aimed at increasing the cross-sectional upper airway volume by advancing the mandible, has an effect on both non-supine AHI and supine AHI. On the other hand, the mode of action of the SPT is preventing the patients from the supine sleeping position. The results show that the time spent in supine position decreased dramatically with the SPT. In some patients, the AHI supine remained still high showing that these patients still have a problem when sleeping in the supine position, but with reducing the time spent in the supine position, the sleep apnea severity decreased in those patients.

The arousals caused by the SPT alone were significantly higher than those by the MAD alone or combination therapy. In addition, the percentage of arousals associated with respiratory events decreased during the study nights with MAD therapy, SPT, and combination SPT + MAD therapy. This indicates that the SPT is associated with an increase in arousals when compared to baseline or MAD therapy, especially those arousals not associated with respiratory events were increased. In future studies, synchronization of the timeline of the SPT with that of the PSG could be of additional interest in order to determine whether or not the arousals are associated with the vibration alarm of the SPT that forces the patient to change body position. In two other studies, one short term (28 days) [14] and one long term (6 months) [29], patients followed a training program to get used to the SPT after which no differences in arousal index were found between baseline and with SPT.

To date, only one paper has been published comparing the efficacy of an oral appliance and positional therapy [5]. In that study, Cartwright et al. [5] described the efficacy of combination therapy of a posture alarm giving an auditory beep when in supine position and a tongue retaining device (TRD), an oral appliance that holds the tongue in a forward position. Patients were assigned to either therapy with the posture alarm, the TRD, or combination therapy with the posture alarm and the TRD. The results of the present RCT are in accordance with the results of Cartwright et al. suggesting that the combination of an oral appliance and positional therapy is better than one of the treatment modalities alone.

Recently, a new classification system for sdOSA was proposed, the Amsterdam Positional OSA Classification (APOC), to classify patients in either true sdOSA patients who could be cured by PT alone or in patients who showed...
benefit from PT but could not be cured and therefore would benefit from combination of therapies [30].

The present study has its limitations. First, a relatively small number of patients was included in this prospective RCT. However, the present study was a proof of concept to evaluate the possible application and first results of this specific combination therapy. Second, the present study did not incorporate an SPT training program, allowing the patients to gradually get used to avoid the supine sleeping position [14]. Third, the MAD was titrated upon subjective resolution of symptoms or until reaching the maximum comfortable limit. The patients selected for this study were treated unsuccessfully and could have needed additional mandibular advancement. However, there was a clear residual sdOSA under MAD therapy. These patients could therefore benefit from additional PT in combination with the MAD instead of further titrating the MAD. Further titration of the MAD includes a risk of more side-effects due to the more advanced mandible. Finally, compliance was not taken into account since the patients were using the SPT the whole night. However, the SPT used in this study includes a feature for measuring compliance objectively, showing a compliance rate at 6-month follow-up of 64.4% in another study [29].

Despite the limitations, the authors stress the clinical relevance of the results of this prospective RCT. In the past, it has been shown that up to one third of patients treated with MAD therapy have sdOSA under therapy [23]. The results of the present study indicate that a combination of SPT + MAD therapy further reduces the sleep apnea severity when compared to the individual treatment modalities. In addition, the success rate with combination therapy increased by up to 65% points when compared to MAD therapy alone. These findings suggest that when patients are unsuccessfully treated with MAD therapy, the presence of sdOSA should be checked and combination SPT + MAD therapy could be suggested in eligible patients. However, further clinical trials are required to assess the applicability, the therapeutic efficacy, and compliance rates at long-term follow-up with this combination therapy, and with other possible combination therapies such as SPT + CPAP therapy.

Conclusions

The results of this prospective randomized controlled trial indicate that the SPT used in this study significantly reduced the time spent in the supine position compared to baseline or MAD therapy. In patients with sdOSA under MAD therapy, both MAD therapy and SPT were individually effective in reducing AHI. However, combination SPT + MAD therapy further reduced the sleep apnea severity and leads to a significantly higher OSA alleviation in patients with sdOSA under MAD therapy.

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