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/m^2) 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.

This study was performed at the St. Lucas Andreas Hospital, Amsterdam, the Netherlands.

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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

TIB   Time in bed
TST   Total sleep time

Introduction

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 increasingly 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

Fig. 1 Subject wearing the Sleep Position Trainer

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)

	Baseline	After SPT	p value
Age, years	48.1±11.0		
Male sex, %	87.1		
BMI	27.0±3.7	27.4±4.0	0.387
Compliance rate, %		92.7 [62.0–100.0]	
AHI, events/h	16.4 [6.6–29.9]	5.2 [0.5–46.5]	<0.001
AHI in supine, events/h	35.7 [9.3–81.0]	0.0 [0.0–100.7]	<0.001
AHI in non-supine, events/h	3.2 [0.0–16.2]	4.3 [0.1–48.0]	0.052
Average oxygen saturation, %	95.1±1.4	95.5±1.6	0.101
Minimum oxygen desaturation, %	84.5±4.1	88.4±3.6	<0.001
Desaturation index, events/h	11.2 [2.2–22.4]	5.2 [0.9–39.6]	<0.001
Apnoea index, events/h	10.4 [1.0–26.3]	2.5 [0.0–21.3]	<0.001
Arousal index, events/h	6.1 [0.0–28.4]	5.5 [0.0–22.8]	0.289
Number of awakenings	4.0 [0.0–60.0]	3.0 [0.0–10.0]	0.323
Total sleep time, min	456±76	429±87	0.187
N2 sleep/total sleep time, %	52.0±8.7	50.0±12.1	0.322
N3 sleep/total sleep time, %	22.4±9.8	21.7±7.7	0.618
REM sleep/total sleep time, %	19.5±5.6	20.9±6.4	0.364
Sleep efficiency, %	89.1 [61.1–99.7]	89.4 [58.0–98.6]	0.544
Percentage supine	49.9 [20.4–77.3]	0.0 [0.0–48.7]	<0.001
Percentage non-supine position	50.1 [22.7–79.6]	100.0 [51.3–100.0]	<0.001
ESS score	11 [2–20]	9 [0–19]	0.004
FOSQ score	86.0±22.1	93.8±21.7	0.001

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

SPT Sleep Position Trainer

Table 2 Individual values of apnoea–hypopnoea index, percentage of supine position, and Epworth Sleepiness Scale scores of all patients at baseline and after 1 month of SPT therapy

Patient no.	AHI		% supine position		ESS		FOSQ	
	Baseline	After SPT	Baseline	After SPT	Baseline	After SPT	Baseline	After SPT
1	6.6	3.3	63.6	12.0	19	19	88	88
2	12.1	5.2	20.5	0.0	16	9	77	78
3	20.2	15.5	65.6	48.7	2	2	85	99
4	16.2	1.8	32.2	0.0	17	18	36	40
5	21.0	10.2	40.0	10.3	14	10	48	72
6	19.0	9.9	28.8	0.1	11	5	90	111
7	20.8	15.4	24.1	2.7	18	19	71	62
8	11.0	10.1	40.5	0.0	12	13	84	92
9	21.0	16.0	56.0	0.0	10	7	101	101
10	11.7	4.3	77.3	0.0	12	12	97	97
11	10.4	0.5	28.7	0.0	17	3	108	118
12	13.4	4.5	70.4	1.3	4	4	111	116
13	24.0	3.5	59.0	0.0	6	3	91	101
14	23.4	9.6	33.5	0.0	15	14	66	74
15	14.5	6.9	21.4	0.0	3	3	119	119
16	16.2	7.6	49.9	7.5	15	13	63	86
17	27.5	4.7	54.5	8.8	5	1	75	80
18	11.8	3.1	20.4	0.0	9	10	73	76
19	18.3	48.4	21.4	4.0	8	4	90	74
20	16.0	19.5	43.8	1.0	7	8	112	120
21	11.9	3.3	57.3	0.0	20	16	82	114
22	29.8	1.9	50.7	0.4	18	9	55	99
23	29.9	8.8	21.2	9.2	12	13	64	75
24	11.1	6.9	71.1	0.0	9	12	59	56
25	6.8	4.9	33.9	0.0	5	0	118	109
26	21.2	2.1	59.5	11.8	11	2	104	120
27	16.6	5.4	68.9	36.3	16	19	105	113
28	11.5	2.0	28.3	10.7	4	1	122	122
29	18.3	1.6	66.5	0.0	8	9	100	108
30	22.9	8.9	55.2	0.0	5	5	70	75
31	10.8	0.7	51.0	0.0	11	4	102	114

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 %. When Sher's criteria of surgical success were used (i.e. the responder group), a 71.0 % (22 of 31) success rate was achieved with a median decrease of 61.1 % in AHI value.

Table 3 Anthropometrical data and clinical and polysomnographic variables in responders and non-responders at baseline and after 1 month

	Responders (n=22)			Non-responders (n=9)			p value[b]
	Baseline	After SPT	p value[a]	Baseline	After SPT	p value[a]	
Age, years	49.8±11.6			44.1±8.6			
Male sex, %	86.4			88.9			
BMI	27.3±3.4			26.3±4.6			
Compliance rate, %	92.9 [61.5–100.0]			96.4 [72.4–100.0]			
AHI, events/h	16.2 [6.6–29.9]	3.9 [0.5–10.3]	<0.001	18.2 [6.7–21.0]	14.1 [4.9–46.5]	0.214	<0.001
AHI in supine, events/h	36.5 [9.3–81.0]	0.0 [0.0–37.3]	<0.001	34.7 [14.9–63.6]	0.0 [0.0–100.7]	0.173	0.685
AHI in non-supine, events/h	3.2 [0.0–16.2]	3.2 [0.1–9.6]	0.833	3.7 [0.2–9.1]	10.1 [3.5–48.0]	0.011	<0.001
Average oxygen saturation, %	95.0±1.5	95.5±1.4	0.004	95.4±1.0	95.2±2.0	0.681	0.620
Minimum oxygen desaturation, %	84.4±4.5	89.4±2.3	<0.001	84.7±3.4	86.0±5.1	0.431	0.087
Desaturation index, events/h	11.2 [2.2–22.4]	4.6 [0.9–13.1]	<0.001	11.6 [5.5–19.0]	8.5 [3.4–39.6]	0.213	0.004
Apnoea index, events/h	11.0 [2.2–26.3]	1.8 [0.0–7.3]	<0.001	8.0 [1.0–19.4]	8.3 [1.6–21.3]	0.953	0.001
Arousal index, events/h	7.5 [3.0–28.4]	5.2 [0.0–20.5]	0.027	0.0 [0.0–18.5]	6.5 [0.0–22.8]	0.176	0.203
Number of awakenings	3.5 [0.0–60.0]	4.0 [1.0–10.0]	0.659	4.0 [0.0–15.0]	1.0 [0.0–9.0]	0.068	0.008
Total sleep time, min	466±80	433±94	0.218	432±63	418±68	0.666	0.656
N2 sleep/total sleep time, %	49.8±8.2	47.3±12.2	0.366	57.3±8.0	56.6±9.5	0.700	0.051
N3 sleep/total sleep time, %	24.7±9.3	23.6±7.4	0.518	16.7±8.8	17.1±6.8	0.846	0.032
REM sleep/total sleep time, %	19.3±5.9	21.0±7.1	0.348	20.1±5.1	20.6±4.4	0.858	0.891
Sleep efficiency, %	88.6 [61.1–99.7]	86.1 [58.0–98.6]	0.306	89.1 [70.1–96.0]	92.0 [68.9–98.1]	0.594	0.086
Percentage supine	50.9 [20.4–77.3]	0.0 [0.0–36.3]	<0.001	40.5 [21.4–71.1]	0.1 [0.0–48.7]	0.008	1.000
Percentage non-supine position	49.2 [22.7–79.6]	100.0 [63.7–100.0]	<0.001	59.5 [29.0–78.6]	99.9 [51.3–100.0]	0.008	0.881
ESS score	12 [3–20]	9 [1–19]	0.007	9 [2–18]	7 [0–19]	0.291	0.623
FOSQ core	84.4±23.6	94.8±21.8	<0.001	90.0±18.6	91.6±22.6	0.710	0.715

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

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[a] Comparing baseline values with values after SPT per group responders/non-responders

[b] Comparing responders with non-responders after SPT
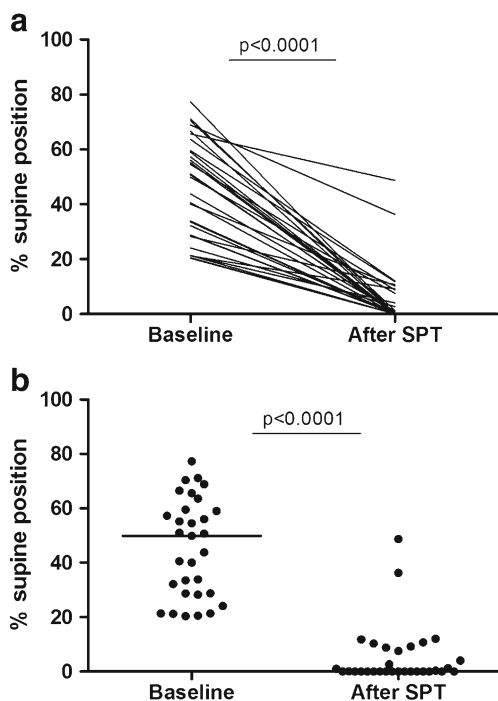
Fig. 2 Effect of SPT therapy on percentage of supine sleeping time. **a** The *lines* depict individual changes in percentage of supine sleeping time from baseline to after 1 month of SPT therapy. **b** The *dots* depict individual percentages of supine sleeping time. The *horizontal black lines* show the median. *SPT* Sleep Position Trainer
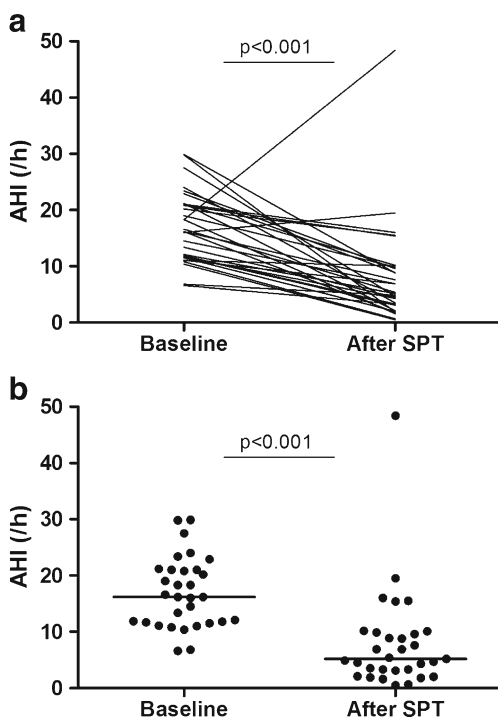
Fig. 3 Effect of SPT therapy on AHI. **a** The *lines* depict individual changes in AHI from baseline to after 1 month of SPT therapy. **b** The *dots* depict individual AHI values. The *horizontal black lines* show the median. *SPT* Sleep Position Trainer, *AHI* apnoea–hypopnoea index

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

Table 4 Comparison of first-generation device and SPT

	First generation	SPT
Device placement	Neck (taped)	Chest (strapped)
Vibrational stimulus	Yes	Yes
Timing vibrational stimulus	After 30 s	Directly
Varying in frequency	No	Yes
Varying in amplitude	Yes	Yes
Training programme	No	Yes
Start delay	No	Yes
Data viewing feedback system	No	Yes

major step forward since the recent study by Permut et al., which showed that positional therapy was equal to CPAP in normalizing the AHI in patients with mild to 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 5.3 %, 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 polysomnographies 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.

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