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Can positional therapy be simple, effective and well tolerated all together? A prospective study on treatment response and compliance in positional sleep apnea with a positioning pillow

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Abstract

Purpose Until now, there is no clear consensus on optimal care for mild sleep-related breathing disorders (SRBD) in general or for positional obstructive sleep apnea (POSA) in particular. Most proposed treatment options are either invasive and/or expensive. Positional therapy (PT) may therefore present as a valuable first-line intervention in POSA.

Methods Twenty-eight patients presenting with POSA were enrolled in a prospective cohort study. The protocol consisted of three nights of polysomnography (PSG) in an academic sleep lab. Inclusion was based on the first PSG. During a consecutive PSG, PT was provided by means of a sleep-positioning pillow (Posiform®). The third PSG was performed after 1 month of PT. Sleepiness, fatigue, and sleep quality were assessed with the Epworth Sleepiness Scale (ESS), the fatigue severity scale (FSS), the Pittsburgh Sleep Quality Index (PSQI), and the Function Outcomes of Sleep Questionnaire (FOSQ) at baseline, and after 1 and at 6 months of PT alongside satisfaction and compliance ratings.

Results Significant immediate treatment effects after one night and sustained after 1 month were observed by significant reductions of sleep in supine position ($p < .001$), sleep fragmentation ($p < .05$), apnea-hypopnea ($p < .001$), respiratory disturbance ($p < .001$), and oxygen desaturation ($p < .001$) indices. PSQI ($p < .001$), ESS ($p < .005$), and FOSQ ($p < .001$) also showed significant and persistent improvements.

Conclusions Combined effects on sleep-related respiration and clinical symptoms were observed after PT initiation as well as after 1 month using the sleep-positioning pillow. Furthermore, reported compliance and overall satisfaction appeared to be highly concordant both at 1 month and 6 months follow-up.

Keywords Positional therapy · Sleep-related breathing disorders · Sleep positioning pillow · Positional obstructive sleep apnea

Introduction

Sleep-related breathing disorders (SRBD) are generally considered to be a continuum of different diagnostic entities or clinical dimensions, mostly categorized by their severity. The latter range from primary snoring and upper airway resistance syndrome (UARS) to obstructive sleep apnea (OSA), often overlapping [1, 2]. Depending upon severity, SRBDs can profoundly impact physical and/or mental health and beget social and economic consequences [3, 4].

Non-invasive ventilation (i.e., continuous positive airway pressure treatment or CPAP) remains among first choice treatments for moderate to severe OSA. Presently, there is no clear consensus about optimal care for milder SRBD in general and positional OSA (POSA) in particular [5, 6]. Among OSA patients, up to 64–69% may present with POSA, according to different classifications [7, 8]. Recently, a new categorization (Amsterdam Positional Obstructive sleep apnea Classification - APOC) for POSA has been developed, aiming at identifying patients that might clinically benefit from PT [8].

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While several interventions, such as oral appliance therapy and upper airway surgery, are either relatively invasive and/or expensive, positional therapy (PT) may be a valuable first-line option for POSA [9–13]. Until recently, the concept of PT was typically based on placing different types of bulky masses in the back. The best-known and most studied example of such a bulky mass is the tennis ball technique (TBT). When used correctly, TBT has shown to significantly reduce supine sleep and apnea-hypopnea index (AHI) [14–16]. In recent years, more sophisticated vibrating chest-strapped and neck-worn devices have been developed and proved to be efficient in POSA management [17–21]. At present, the most studied device is the chest-strapped sleep position trainer (SPT), which showed to be as effective as TBT and displayed sustained effects and satisfying compliance rates over 6 months along with higher tolerance than classic TBT [22, 23].

Only three studies investigated the use of different sleep positioning pillows. Zuberi et al. reported significant reduction in respiratory disturbance, reduced hypoxemia, and snoring after one night with a triangular pillow (SONA®) in 22 patients presenting with mild to moderate OSA [24]. A second study investigated one night of PT with the SONA® pillow in a sample of 18 recent post-stroke patients. OSA screening with a portable monitor showed a significant reduction of supine position and AHI, and self-reported adherence 3 months post-stroke was documented in the nine subjects that were randomized to the active PT group [25]. Thirdly, the use of a head positioning pillow for two consecutive nights in 25 mild to moderate POSA patients showed significant reductions of subjective and objective snoring severity in normal-weight patients, in contrast to overweight patients where only a reduction in subjective snoring was shown [26].

Hence, since many different devices, based on various principles and techniques, co-exist, PT has yet to become standardized. Compliance issues, mainly due to discomfort, also frequently hamper PT. Moreover, follow-up studies recording compliance rates and perceived treatment efficacy remain sparse within the field of PT in POSA.

To these extents, the present study aims at prospectively investigating the effects of a sleep-positioning pillow on both respiratory variables and sleep architecture (baseline, consecutive treatment response, and follow-up polysomnographies) along with structured clinical scales. In addition, 1 and 6-month follow-up compliance, and both patient and bed partner satisfaction will be assessed.

Methods

Study design

Inclusion of patients was based on the results of a first diagnostic polysomnography (PSG; baseline, t_0), completion of a clinical questionnaire as well as routine clinical examination. Moreover, all patients completed a selection of symptom scales (Fatigue Severity Scale (FSS), Epworth Sleepiness Scale (ESS), Pittsburgh Sleep Quality Index (PSQI), Functional Outcomes of Sleep Questionnaire (FOSQ-10), reported compliance (number of days per week), overall satisfaction of both patient and bed partner (visual analogue scale (VAS) between 0 and 10)). Patients meeting inclusion criteria were given a sleep-positioning pillow for a consecutive PSG (intervention night, t_1), after giving informed consent. Patients returned home with the positioning pillow and were instructed to use it whenever possible. After 1 month (t_2), patients returned to the sleep lab for a follow-up PSG under PT (Fig. 1). Compliance rates, and personal and bed partner's overall satisfaction along with symptom evaluations were collected. All PSGs were performed in the same laboratory under analogous conditions. Subsequently, after 6 months (t_3), a final follow-up questionnaire containing symptom scales reported compliance and overall satisfaction was sent and returned by mail.

Subjects

Between August 2015 and May 2016, inclusion comprised tertiary care referral of patients between 18 and 70 years old for suspected SRBD and daytime complaints either of fatigue, sleepiness or non-restorative sleep, or combinations of the aforementioned symptoms. Inclusion thresholds were defined by the diagnosis of mild to moderate OSA ($20 > \text{AHI} \geq 5$) after the first PSG. The presence of a significant positional component (difference of 50% or more in AHI between supine and non-supine positions, and > 10% of TST in both best sleeping position (BSP) and worst sleeping position (WSP) as defined by APOC I (BSP AHI < 5) or APOC II (BSP AHI in a lower OSA severity category) criteria during the first PSG recording) was mandatory.

CPAP trial is routinely proposed for moderate to severe OSA ($\text{AHI} \geq 20$) patients in the context of local reimbursement criteria. Exclusion criteria other than CPAP trials are any comorbid sleep disorder other than SRBD, central sleep apnea, body mass index ($\text{BMI}) \geq 40$, any other overlapping severe and sleep interfering medical condition, or comorbid mental disorder. Patients who underwent current or recorded past (for less than 2 weeks prior to admission to the sleep laboratory) sleep interfering drug treatments were also excluded, as well as substance abuse and a consumption of more than 2 U of alcohol per day. All included patients were formerly undiagnosed and untreated for SRBD.

Sleep positioning pillow

The sleep positioning pillow (Posiform®, Oscimed S.A. (Inc.) ™, La Chaux-de-Fonds, Switzerland – Fig. 2) is made of natural memory foam (100% polyester) concealed under a removable 100% cotton cover and a second anti-sweat velvet-

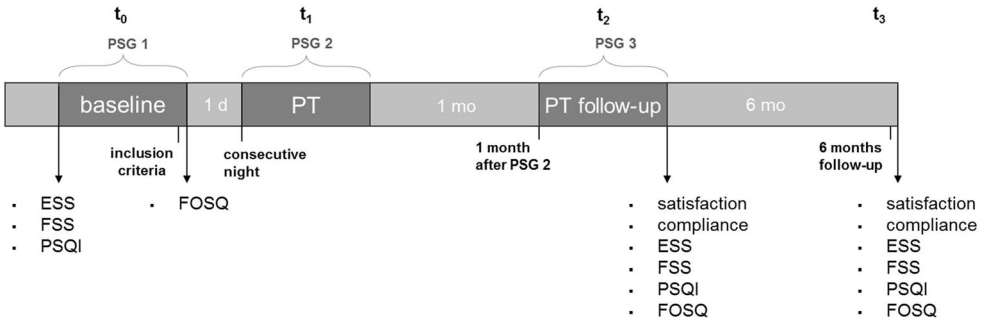

Fig. 1 Study design timeline. Measure points t_0, t_1, t_2, and t_3 indicate recorded polysomnography (PSG) and/or administration of structured clinical or visual analog (VAS) scales (see "Methods" section) and compliance reports. Dark gray areas indicate baseline, positional therapy (PT), and follow-up PSG under PT

bamboo coating. Aside from the central ridge (i.e., comparable function to a bulky mass placed in the back), it has two inclined concave and flattened surfaces consisting of a frontal support, a neck support, and a recess for the shoulder as well as for nose and mouth. Its dimensions are 55 cm long, 31 cm wide, 12 cm high at the highest point of the ridge, and 7.5 cm high at the lowest point of the inclined flattened surfaces.

Material

PSG recordings included at least three electroencephalograms recorded from Fp2-Ax, C4-Ax, O2-Ax sites, two electrooculograms, submental, and bilateral anterior tibial electromyograms. Oral and nasal airflow were recorded by a oro-nasal cannula (Pro-Flow Plus™ Pro-Tech® Mukilteo, WA, USA), and respiratory effort was measured by thoracic and abdominal belts (Pro-Tech® CT2™, Mukilteo, WA, USA). Capillary oxygen saturation was monitored by photosensitive fingeroximetry (Nonin® Flexi-Form® II 7000A Nonin Medical Inc., Minneapolis, MN USA and LINOP® Adt Masimo corp. Irvine, CA, USA). All PSG recordings were analyzed on 21″ screens displaying 30-s epochs (Philips Respironics Inc.™ Alice6® and SleepwareG3®, Philips Healthcare™, Eindhoven, The Netherlands, European Union) by trained technicians unaware of the aims of the study.

Polysomnography

Sleep onset latency (SOL) was defined as the time between lights off and the first epoch of sleep. Wake time did not include sleep latency (Wake after sleep onset, WASO). Sleep efficiency (SEI) were defined by TST divided by time in bed (TIB). Time spent sleeping in supine and non-supine position was defined in % of TST (TST-S and TST-NS). NREMS (non-rapid eye movement sleep) included sleep stages N1, N2, and N3 (or slow wave sleep, SWS). REMS (rapid eye movement sleep) latency (REMLAT) was defined as the time between sleep onset and the first epoch of REMS. An episode of sleep apnea was defined as a 90% reduction or an absence in airflow for at least 10 s during sleep. A sleep hypopnea was defined by a drop of 30% or more of the peak signal excursions of pre-event baseline for at least 10 s during sleep accompanied by either a 3% or greater reduction in oxygen saturation and/or an arousal. Furthermore, a distinction was made between apneas of obstructive, central, and mixed origin, as well as the AHI in supine and non-supine position (AHI-S and AHI-NS). A respiratory-related arousal (RERA) was characterized by an increased respiratory effort or flattening of the inspiratory portion of the nasal pressure for at least 10 s leading to an arousal from sleep. Snoring was defined by the percentage of TST

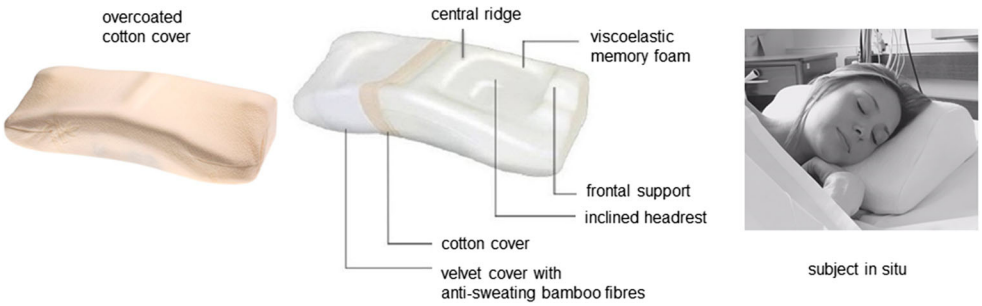

Fig. 2 Sleep-positioning pillow. Figure 2 depicts the sleep-positioning pillow (Posiform®), studied for PT in included POSA patients. From left to right: visual aspect of the pillow's external cotton cover; observable underlying foam structure beneath illustrated velvet cover; subject's head and neck placement in lateral position

where vibrations were detected by a piezo-electric sensor placed on the throat, and again, a distinction was made between snoring in supine and non-supine position (snoring-S and snoring-NS). The arousal index (ArI) represented the number of microarousals per hour of sleep. Arousals were defined according to the American Academy of Sleep Medicine (AASM) criteria [27]. AHI was defined by the number of apneas and hypopneas per hour of sleep, RDI was defined as the number of apneas, hypopneas, and RERAs per hour of sleep, and the oxygen desaturation index (ODI) was defined as the number of arterial desaturation events of 3% or more per hour of sleep. Minimal (Min) and average (Mean) SaO_2 were also recorded by means of photo-oximetry. UARS and OSA were diagnosed according to ICSD criteria with respectively an RDI and an AHI greater than or equal to 5 [26]. All diagnoses of (primary and co morbid) insomnia, hypersomnia, periodic leg movement disorder (PLMD), and restless leg syndrome (RLS) as exclusion criteria were made according to ICSD/DSM criteria [27, 28].

Statistics

A sample size of min. of 16 patients completing the study (three measure points; estimated $r = .50$ among repeated measures) was planned a priori to detect effects explaining at least 10% of the variance ($\eta^2_p > .10$), assuming a power of 80%, an alpha of 5%, and tested two-sidedly. A priori sample size calculation was performed using G*Power 3.1.9.2 [29].

Normality was assessed by means of Kolmogorov-Smirnov tests and visual inspection of P-P plots. Normally, distributed data are reported as mean ± (standard deviation) and non-normally distributed variables as median (quartile1; quartile3). Treatment effects on PSG variables and symptom scales were investigated using a Generalized Linear Model (GzLM) with time as fixed effect and subjects as random effects. The model was estimated using robust maximum likelihood (RML) with Satterthwaite approximation to correct *df*s for small samples and a sequential Bonferroni correction for multiple comparisons. The GzLM approaches data differently in case of unbalanced designs (in this case data missing at random; MAR) compared to the general linear model (GLM). Instead of dropping a complete case if any cell is missing, only the specific time point missing is removed from the analysis. The remaining data is retained for model estimation and allows for specifying average time trends per individual. Explorative correlations were computed using Pearson's moment *r*. Significance levels for hypotheses tests were set at 5%, and trends were reported at the 10% level. All statistical analyses were performed with SPSS 24® (International Business Machines, IBM™ Inc., Armonk, NY, USA).

Results

Subjects

Twenty-eight patients were included in a prospective cohort-study protocol (17 males; mean age 51.5 ± 10.8 years; mean body mass index 28.9 ± 4.6; see Table 1). Four patients discontinued the protocol after the second PSG because of the required subsequent follow-up PSG after 1 month, and only one due to experienced discomfort (neck pain). Three patients did not return to the sleep lab upon request for the follow-up PSG after 1 month (one due to the same experienced discomfort, one due to a lack of perceived efficacy of PT, and one for unknown reasons). As a result of neck pain, one patient interrupted the use of the sleep-positioning pillow before the 6 months follow-up and one additional patient failed to return the questionnaires at 6 months, despite oral report of high compliance and satisfaction rates.

Compliance and satisfaction rates

Maintained reported average durations (days per week) for pillow use after 1 month (6.75 ± 0.6) and at 6 months (6.17 ± 1.8), respectively ($F(1,24) = 1.898$, p = ns), were shown. Analogous results were observed for average hourly nighttime use after 1 month (7.39 ± 0.9) and at 6 months (6.89 ± 1.9), $F(1,31) = 2.004$, p = ns. When defining compliance as a nightly use of more than 4 h per night and a use of more than five nights a week, 78% of the patients in our study met these criteria after 1 month, and 74% at 6 months (p = ns). Overall subjective satisfaction ratings on auto- and hetero-evaluation VAS show similar mean scores (cm, ranging between 0 and 10) between patients and bed partners (BP) at both measure points, at 1 month (patients = 7.78 ± 1.5; BP = 6.39 ± 3.2) and at 6 months (patients = 7.28 ± 2.5; BP = 6.1 ± 3.6), respectively: No significant main effects of time, BP, nor interaction (time × BP) have been found ($F_{time}(1,17) = .922$, p = ns; $F_{BP}(1,17) = 2.349$, p = ns; $F_{time*BP}(1,17) = .507$, p = ns). All but two of the included patients were found to have regular bed partners.

Table 1 Descriptives

Age (years)	51.5 ± 10.8
Gender ratio	61% male
BMI (kg/m^2)	28.9 ± 4.6
Neck circumference (cm)	39.6 ± 3.0
APOC classification	APOC I: 27 subjects; APOC II: 1 subject

Amsterdam Positional Obstructive sleep apnea Classification (APOC); > 10% of total sleep time both in best and worst sleep position as well as apnea/hypopnea index < 5 in best sleep position (APOC I); > 10% of total sleep time in both best and worst sleep position as well as apnea/hypopnea index of best sleep position in a lower obstructive sleep apnea category than overall apnea/hypopnea index (APOC II) and body mass index (BMI)

Treatment outcome

Clinical remission defined by an AHI < 5/h was obtained in 50% of the included patients after one night and remained stable at 1 month follow-up. An additional treatment response defined by > 50% reduction in AHI was observed in 15% of the initial inclusions after one night and was maintained at 1 month follow-up (20%). However, also 20% of the patients who completed the entire study protocol proved to be non-responders to PT defined by a reduction in AHI inferior to 30% at the 1 month follow-up. The mean disease alleviation (MDA) is a measure of overall therapeutic effectiveness, calculated by the product of adjusted compliance (the average of reported pillow compliance/use in hours per day and days per week [i.e., subjective TST] divided by the average TST as recorded by PSG [i.e., objective TST]) and therapeutic efficacy (difference between baseline AHI and AHI under PT, expressed in percentage). At the 1 month follow-up measure point, the calculated MDA is 55.03%.

Polysomnography

Omnibus tests on PSG variables at t_0 (baseline), t_1 (PT), and t_2 (after 1 month of PT) show a significant decrease in percentage of TST-S, ArI, AHI, RDI, and ODI, as well as a significant increase in percentage of TST-NS. After one night of PT, a reduction of AHI and TST-S of respectively 43 and 47% was observed compared to baseline, and this reduction in TST-S even elevated to 57% at 1 month follow-up. A significant increase in Mean SaO_2 and Min SaO_2 was equally observed (Table 2). Post hoc comparisons show statistical differences both between t_0 and t_1 and between t_0 and t_2 measure points for TST-S, ArI, AHI, HI, RDI, and Min SaO_2. Statistically significant post hoc effects between t_0 and t_1 only are found for ODI and Mean SaO_2 (Fig. 3). In addition, omnibus tests reveal a trend for decreased sleep onset latency (SOL), increased sleep stage N1 and decreased OAI and CAI. All other comparisons returned statistically not significant (Table 2).

Symptom scales

Perceived sleep quality (PSQI), impact of sleepiness on daily life (FOSQ), and daytime sleepiness (ESS) all show statistically significant improvements on omnibus tests (Table 3). Post hoc comparisons (Fig. 4) between measurements at t_0, t_2, and t_3 reveal statistically significant improvement between baseline (t_0) and 1 month of PT (t_2) and between baseline and 6 months (t_3) of PT for PSQI, FOSQ, and ESS. All other tests returned statistically not significant (Fig. 4).

Pairwise correlations

Explorative correlations between symptom scales and sleep variables show statistically significant relations between the improvement of perceived sleep quality (PSQI) and hypoxemia (Min SaO_2) reduction ($r = -.572$, $p < .005$) under PT. Increased subjective sleep quality, as evidenced by the slope of PSQI levels, and reported PT application (number of days per week) are also both significantly correlated to average SaO2 (Mean SaO_2) levels during sleep ($r = -.539$, $p < .010$ and $r = .556$, $p < .010$, respectively).

Discussion

To our knowledge, this is the first long-term follow-up study protocol with a sleep positioning pillow, combing PSG data, structured symptom scales, along with reported compliance levels and satisfaction ratings. Most of sleep-related respiratory parameters (i.e., AHI, RDI, ODI, Mean SaO_2, Min SaO_2) and sleep fragmentation (ArI) showed significant immediate effects of PT with the pillow and maintained improvements after 1 month of home use.

Immediate and sustained effectiveness of the positioning pillow was confirmed by significantly less time spent sleeping in supine position after one night and 1 month. In line with previous reports about PT [18–21, 25, 30], overall AHI decreased significantly after one night with the positioning pillow. Remission of POSA (AHI < 5/h) has previously been reported for TBT and SPT [23]. In our sample, half of the patients obtained a remitted AHI after one night of PT and maintained remission after 1 month. When comparing the efficacy of the positioning pillow to the newer vibro-tactile devices, the latter are superior in reducing AHI and TST-S after one night of usage (respectively 43 vs 54% and 47 vs 84%) [21]. Eijsvogel et al. (2015) reported a MDA of 48.6% for TBT and of 70.5% for the SPT at a 1 month follow-up of PT [23]. With respect to these former results, the MDA of the positioning pillow at 1 month follow-up (55.03%; see results section) appears to be numerically superior to TBT, but lower than SPT. With respect to patients' cost exposure, it may be worthwhile to mention that the average pricing of the studied pillow represents a fraction of the investment for vibro-tactile devices such as the SPT.

Commonly, the main complaint of patients addressed to the sleep lab suffering from mild to moderate SRBD is reported snoring. Conversely snoring gradually improved only numerically from the first night of PT to 1 month follow-up. The previously mentioned neck-based device also only showed a trend in snoring reduction, both after 1 week and after 1 month of home use [19]. In three different studies about the chest-worn SPT as well as in one of the studies about the triangular pillow (SONA®), snoring is not reported at all [17, 18, 25]. In two previous reports about pillows, significant reductions in

Table 2 Polysomnographic variables

	Baseline (t_0)		Positional treatment (t_1)		1-month follow-up (t_2)			
	($n = 28$)		($n = 28$)		($n = 20$)			
							F	p
TIB (min)	507.9	(490.7; 549.4)	499.3	(484.1; 520.5)	498.5	(485.7; 524.0)	2.187	ns
TST (min)	395.2	(67.5)	401.5	(67.1)	358.4	(115.1)	2.056	ns
TST-S (%)	47.5	(21.2)	19.2	(10.6; 41.8)	20.4	19.6	17.478	.001
TST-NS (%)	52.5	(21.2)	74.7	(19.7)	79.6	19.1	17.478	.001
SOL (min)	35.7	(18; 49.7)	17.8	(9.8; 33.3)	16.7	(10.1; 58.2)	2.422	(.096)
WASO (min)	38.5	(29.1; 60.6)	47.0	(38.0; 85.0)	50.5	(32.4)	0.589	ns
SEI (%)	75.3	(11.6)	78.1	(10.1)	73.0	(14.2)	2.000	ns
N1 (%)	17.5	(6.5)	12.3	(7.2; 19.4)	20.2	(11.5)	2.799	(.071)
N2 (%)	50.7	(10.1)	53.7	(10.4)	54.4	(43.6; 57.9)	1.280	ns
N3 (%)	18.3	(9.0)	16.6	(10.8; 19.6)	15.7	(6.4)	1.269	ns
REM (%)	13.5	(5.1)	13.0	(5.7)	14.4	(5.8)	0.514	ns
ArI (events/h)	20.6	(6.2)	17.7	(6.0)	16.7	(6.7)	5.112	.008
AHI (events/h)	12.1	(3.8)	6.4	(3.9; 9.8)	6.0	(3.5; 13.0)	13.403	.000
AHI-S (events/h)	25.2	(13.7)	14.6	(5.9; 24.6)	23.0	(18.4)	0.512	ns
AHI-NS (events/h)	3.4	(2.7)	3.3	(2.0)	3.7	(3.4)	0.216	ns
OAI (events/h)	2.3	(2.3)	1.2	(1.6)	0.6	(0.3; 1.9)	3.076	(.054)
CAI (events/h)	0.3	(0.2; 0.9)	0.2	(0.0; 0.5)	0.0	(0.0; 0.2)	2.546	(.087)
MAI (events/h)	0.05	(0.0; 0.3)	0.1	(0.0; 0.2)	0.0	(0.0; 0.2)	0.232	ns
HI (events/h)	8.8	(3.4)	3.7	(3.1; 6.4)	4.3	(1.9; 8.0)	12.229	.001
RDI (events/h)	18.4	(5.6)	11.5	(4.6)	12.9	(8.4)	16.200	.001
ODI (events/h)	6.1	(3.1)	2.8	(1.8; 4)	3.4	(1.4; 6.6)	15.211	.001
Mean SaO_2 (%)	93.8	(1.6)	94.8	(1.5)	94.0	(94.0; 95.0)	7.521	.001
Min SaO_2 (%)	87.0	(84.0; 89.0)	90.1	(2.5)	90.0	(2.3)	7.504	.001
Snoring (%)	26.3	(18.6)	21.5	(17.1)	20.4	(22.6)	1.216	ns
Snoring-S (%)	40.8	(25.1)	35.0	(28.1)	28.3	(27.7)	2.313	ns
Snoring-NS (%)	9.5	(12.2)	15.2	(16.3)	14.1	(20.6)	0.142	ns

With some of the measure specifications made between *S* (supine position) and *NS* (non-supine position). Results are expressed as mean (standard deviation) or as median (Q1; Q3)

Comparison of repeated measures of *AHI* total apnea-hypopnea index, *ArI* arousal index, *CAI* central apnea index, *HI* hypopnea index, *MAI* mixed arousal index, *Mean SaO_2* mean oxygen saturation, *Minimal SaO_2* minimal oxygen saturation, *N1* sleep stage 1, *N2* sleep stage 2, *N3* sleep stage 3, *OAI* obstructive apnea index, *ODI* oxygen desaturation index, *REM* rapid eye movement, *RDI* respiratory disturbance index, *SEI* sleep efficiency index, *SOL* sleep onset latency, *TIB* time in bed, *TST* total sleep time and *WASO* wake time after sleep onset

snoring after one night in a sleep lab or two consecutive nights at home were reported [24, 26].

Alongside with improved sleep-related respiratory function, a significant reduction of sleep fragmentation (ArI) was also observed for both PSG measures (first treatment night and 1 month follow-up) under PT. As further evidenced by the stability of classical sleep variables (i.e., similar TST, sleep efficiencies, and WASO) across conditions (baseline, PT, and follow-up PT), the positioning pillow did not negatively impact sleep duration or maintenance. Conversely, the chest-worn SPT did not show improvements on sleep architecture parameters [18]. At last, two studies investigating positioning pillows were performed without PSG, failing to provide reports on sleep architecture [25, 26]. Although Zuberi et al. performed PSG recordings, no sleep architecture parameters were reported [24].

Besides PSG-derived variables, we observed a reduction of daytime sleepiness (ESS) below clinical thresholds along with significant improvements of sleep quality and related quality of life (PSQI, FOSQ), both after 1 and 6 months of using the positioning pillow. Similar results were reported by van Maanen et al. [18] and van Maanen and De Vries [22] using the chest-strapped SPT. Moreover, in our study, enhanced sleep quality (PSQI) was correlated to reduced nocturnal hypoxemia under PT. While not reporting sleep quality assessments, studies about a neck-based device only showed a trend in improving daytime sleepiness [19, 20].

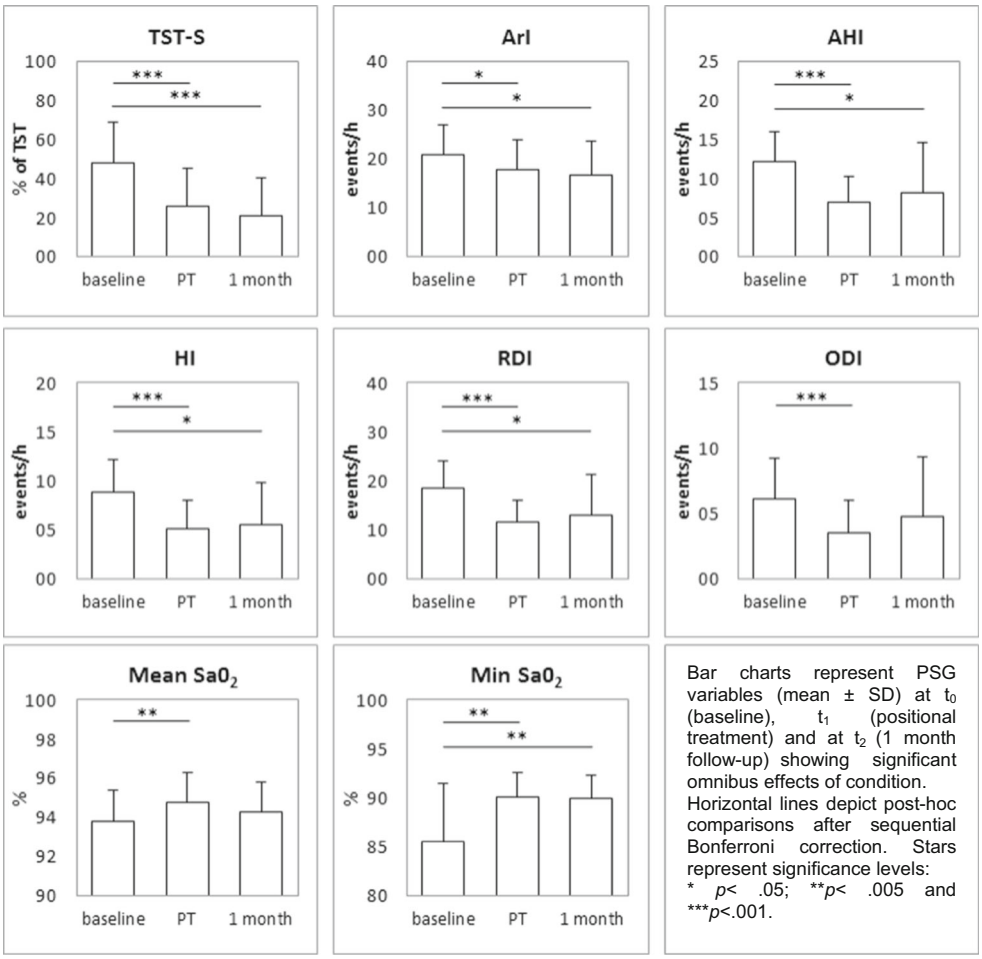

Fig. 3 Immediate and follow-up effects of PT on sleep and breathing. Post hoc comparisons for total sleep time (TST) in supine (S) expressed in percentage of TST; arousal, apnea-hypopnea, hypopnea, respiratory disturbance and oxygen desaturation indices (ArI, AHI, HI, RDI, and ODI, respectively) in events per hour; mean and minimal oxygen saturation (Mean SaO_2 and Min SaO_2, respectively) in percent

Given the limited study duration of two of the other protocols involving sleep-positioning pillows (respectively 1 and 2 days), there were no available data reports on compliance or overall satisfaction ratings [24, 26]. When defining compliance as a nightly use of more than 4 h and a use of more than five nights a week, roughly four out of five patients in our study met these criteria after 1 month, and three out of four at 6 months. Compliance rates did not show further significant differences between both follow-up evaluations. Hence, in line with follow-up reports on objective compliances measured by build-in instruments, we found quite akin subjective compliance rates at 6 months [22]. To our knowledge, however, we firstly reported not only overall patient satisfaction but also ratings from bed partners, both at 1 and 6 months follow-up. Satisfaction levels were high, statistically similar between patients and their bed partners, and remained stable over time.

Table 3 Symptom scales

	Baseline		1-month follow-up		6-months follow-up			
	(n = 28)		(n = 20)		(n = 18)			
	M	SD	M	SD	M	SD	F	p
PSQI	7.4	3.2	4.6	2.1	4.8	2.2	15.253	.000
FOSQ	14.8	3.2	17.1	2.4	17.2	2.3	8.455	.001
ESS	11.1	5.1	8.0	4.6	7.2	4.3	7.164	.002
FSS	4.0	1.3	3.5	1.7	3.6	1.3	0.805	ns

Comparison on repeated measures of psychometric assessments, at t_0 (baseline), t_2 (1-month follow-up), and t_3 (6-months follow-up) for the Epworth Sleepiness Scale (ESS), the Fatigue Severity Scale (FSS), the Functional Outcomes of Sleep Questionnaire (FOSQ), and Pittsburgh Sleep Quality Index (PSQI)

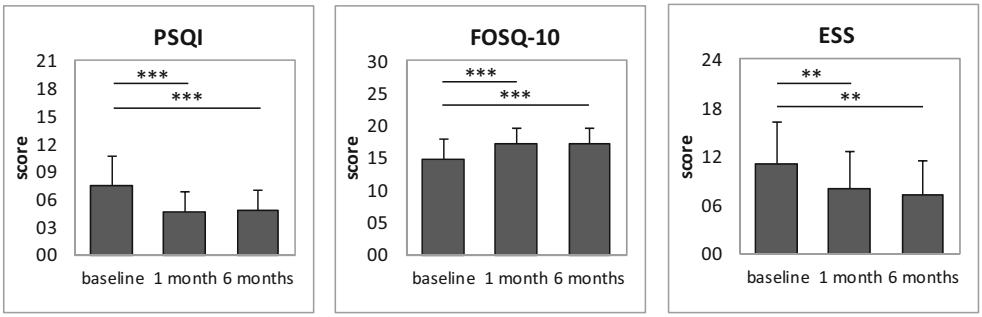

Fig. 4 Long-term evolution of clinical symptoms. Bar charts represent scores of psychometric measures (mean ± SD) at t_0 (baseline), t_2 (1-month follow-up), and at t_3 (6 months follow-up) showing significant omnibus effects of condition on the Epworth Sleepiness Scale (ESS), the Functional Outcomes of Sleep Questionnaire (FOSQ), and the Pittsburgh Sleep Quality Index (PSQI). Horizontal lines depict post hoc comparisons after sequential Bonferroni correction at $p < .05$ (*), $p < .005$ (**), and $p < .001$ (***) significance levels, respectively

Limitations of our investigation may be related to the limited sample size, the drop-out rate mainly at the start of the study, or to an eventually lacking direct head-to-head comparison between different PT devices. However, the latter was not the aim of the present study, and thorough selection procedure led to a homogeneous sample of POSA patients in order to reduce measurement error. The absence of an objective compliance record (i.e., pressure sensors in the pillow) as a result of the device design implies an additional limitation here, the latter leading to a lower reliability of compliance data collection in comparison to the vibrotactile devices (i.e., build-in accelerometer and data storage), which may therefore overestimate the MDA. However, follow-up PT studies with more than two PSG recordings remain scarce in general, and systematic evaluation with structured clinical scales or satisfaction reports is, to our knowledge, still completely lacking when studying sleep positional pillows in particular.

Conclusions

In summary, we showed significant treatment effects in POSA with a sleep-positioning pillow (Posiform®). By significantly limiting sleep in supine position, this low-cost PT reduced sleep-related respiratory events and associated sleep fragmentation and improved nocturnal oxygen levels during sleep along with normalized perceived sleep quality and resolved excessive daytime sleepiness. Immediate treatment responses on sleep variables evidenced by PSG were reproducible at a 1-month follow-up PSG. Concomitantly, satisfaction ratings from both patients and bed partners were high, and compliance reports remained stable over a 6-month period.

At last, this positioning pillow is not the sole PT option in POSA. However, results of our prospective study demonstrated that a simple accessory might not only be well tolerated but also a consistently efficacious alternative, deserving consideration as a first-line treatment.

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Compliance with ethical standards

Conflict of interest All authors certify that they have no affiliations with or involvement in any organization or entity with any financial interest (such as honoraria; educational grants; participation in speakers' bureaus; membership, employment, consultancies, stock ownership, or other equity interest; and expert testimony or patent-licensing arrangements), or non-financial interest (such as personal or professional relationships, affiliations, knowledge, or beliefs) in the subject matter or materials discussed in this manuscript.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study.

References

1. Anstead N, Phillips B (1999) The spectrum of sleep-disordered breathing. Resp Care Clin N Am 5:363–377
2. De Godoy LB et al (2015) Treatment of upper airway resistance syndrome in adults: where do we stand? Sleep Sci 8:42–48
3. Kendzerska T, Mollayeva T, Gershon AS, Leung RS, Hawker G, Tomlinson G (2014) Untreated obstructive sleep apnea and the risk for serious long-term adverse outcomes: a systematic review. Sleep Med Rev 18:49–59
4. Conwell WD, Tsai SC (2016) Managing comorbid illness in obstructive sleep apnea: what can we learn from other diseases? Sleep Med Clin 11:313–321
5. Weaver TE et al (2014) Innovative treatments for adults with obstructive sleep apnea. Nat Sci Sleep 18:137–147

6. McNicholas WT, Bonsignore MR, Lévy P, Ryan S (2016) Mild obstructive sleep apnoea: clinical relevance and approaches to management. Lancet Resp Med 4:826–834
7. Catwright RD (1984) Effect of sleep position on sleep apnea severity. Sleep 7:110–114
8. Ravesloot MJ et al (2016) Positional OSA part 2: retrospective cohort analysis with a new classification system (APOC). Sleep Breath 20:881–888
9. Ravesloot MJ, van Maanen JP, Dun L, de Vries N (2013) The undervalued potential of positional therapy in position-dependent snoring and obstructive sleep apnea-a review of the literature. Sleep Breath 17:39–49
10. Oksenberg A, Gadoth N (2014) Are we missing a simple treatment for most adult sleep apnea patients? The avoidance of the supine sleep position. J Sleep Res 23:204–210
11. Joosten SA, O'Driscoll DM, Berger PJ, Hamilton GS (2014) Supine position related obstructive sleep apnea in adults: pathogenesis and treatment. Sleep Med Rev 18:7–17
12. Spicuzza L, Caruso D, Di Maria G (2015) Obstructive sleep apnoea syndrome and its management. Ther Adv Chronic Dis 6:273–285
13. Barnes H, Edwards B, Joosten S, Naughton M, Hamilton G, Dabscheck E (2016) Positional modification techniques for supine obstructive sleep apnea: a systematic review and meta-analysis. Sleep Med Rev 36:107–115. https://doi.org/10.1016/j.smrv.2016.11.004
14. Skinner MA, Kingshott RN, Filsell S, Taylor DR (2008) Efficacy of the 'tennis ball technique' versus nCPAP in the management of position-dependent obstructive sleep apnoea syndrome. Respirology 13:708–713
15. Bignold JJ, Deans-Costi G, Goldsworthy MR, Robertson CA, McEvoy D, Catcheside PG, Mercer JD (2009) Poor long-term patient compliance with the tennis ball technique for treating positional obstructive sleep apnea. J Clin Sleep Med 5:428–430
16. Jackson M, Collins A, Berlowitz D, Howard M, O'Donoghue F, Barnes M (2015) Efficacy of sleep position modification to treat positional obstructive sleep apnea. Sleep Med 16:545–552
17. Bignold JJ, Mercer JD, Antic NA, McEvoy RD, Catcheside PG (2011) Accurate position monitoring and improved supine-dependent obstructive sleep apnea with a new position recording and supine avoidance device. J Clin Sleep Med 7:376–383
18. van Maanen JP et al (2012) Evaluation of a new simple treatment for positional sleep apnea patients. J Sleep Res 21:322–329
19. Levendowski DJ, Seagraves S, Popovic D, Westbrook PR (2014) Assessment of a neck-based treatment and monitoring device for positional obstructive sleep apnea. J Clin Sleep Med 10:863–871
20. Scarlata S, Rossi Bartoli I, Santangelo S, Giannunzio G, Pedone C, Antonelli Incalzi R (2016) Short-term effects of a vibrotactile neck-based treatment device for positional obstructive sleep apnea: preliminary data on tolerability and efficacy. J Thorac Dis 8:1820–1824
21. Ravesloot MJ, White D, Heinzer R, Oksenberg A, Pépin JL (2017) Efficacy of the new generation of devices for positional therapy for patients with positional obstructive sleep apnea: a systematic review of the literature and meta-analysis. J Clin Sleep Med 13:813–824
22. van Maanen JP, de Vries N (2014) Long-term effectiveness and compliance of positional therapy with the sleep position trainer in the treatment of positional obstructive sleep apnea syndrome. Sleep 37:1209–1215
23. Eijsvogel MM, Ubbink R, Dekker J, Oppersma E, de Jongh FH, van der Palen J, Brusse-Keizer MG (2015) Sleep position trainer versus tennis ball technique in positional obstructive sleep apnea syndrome. J Clin Sleep Med 11:139–147
24. Zuberi NA, Rekab K, Nguyen HV (2004) Sleep apnea avoidance pillow effects on obstructive sleep apnea syndrome and snoring. Sleep Breath 8:201–207
25. Svatikova A, Chervin RD, Wing JJ, Sanchez BN, Migda EM, Brown DL (2011) Positional therapy in ischemic stroke patients with obstructive sleep apnea. Sleep Med 12:262–266
26. Chen WC et al (2015) Treatment of snoring with positional therapy in patients with positional obstructive sleep apnea syndrome. Sci Rep 11:181–188
27. Berry RB, and the American Academy of Sleep Medicine et al (2012) Rules for scoring respiratory events in sleep: update of the 2007 AASM Manual for the Scoring of Sleep and Associated Events. Deliberations of the Sleep Apnea Definitions Task Force of the American Academy of Sleep Medicine. J Clin Sleep Med 8:597–619
28. American Psychiatric Association (APA) (2013) Diagnostic and statistical manual of mental disorders, 5th edn. American Psychiatric Publishing, Arlington
29. Faul F, Erdfelder E, Lang AG, Buchner A (2007) G*power 3: a flexible statistical power analysis program for the social, behavioral, and biomedical sciences. Behav Res Methods 39:175–191
30. Heinzer RC, Pellaton C, Rey V, Rossetti AO, Lecciso G, Haba-Rubio J, Tafti M, Lavigne G (2012) Positional therapy for obstructive sleep apnea: an objective measurement of patients' usage and efficacy at home. Sleep Med 13:425–428