

First comparison of the Velumount[®] palatal device with continuous positive airway pressure (CPAP), repetition effect in neuropsychological tests, and comparative study factors

Cristina Staub

ENT Clinic, Cantonal Hospital, Liestal, Switzerland

cristina.staub@solnet.ch

ABSTRACT

Data of 18 patients with obstructive sleep apnea syndrome (OSAS) on therapy with continuous positive airway pressure (CPAP) (with good efficacy) and with the Velumount[®] device were collected by respiratory polygraphy, blood pressure measurement, questionnaires, and neuropsychological tests to compare for the first time the effects of the Velumount[®] device to the one of CPAP therapy. Number of side effects ($p < 0.001$), oxygen saturation ($p < 0.01$), and systolic blood pressure ($p < 0.05$) significantly decreased with the Velumount[®] device. Compliance, therapy satisfaction, and apnea-hypopnea index significantly (AHI; $p < 0.01$) increased with the Velumount[®] device. There was no significant difference in the proposed compliance adjusted AHI. Average improvements in neuropsychological performance lay within the range of the repetition effect. Alternatives to CPAP therapy (such as the Velumount[®] device) should be individually adapted to OSAS patients. The proposed comparative study factors should be considered in required follow-up comparative studies.

Keywords: Obstructive sleep apnea syndrome (OSAS); Continuous positive airway pressure (CPAP) and Velumount[®] palatal device; Repetition effect in neuropsychological tests; Comparative study factors; Compliance adjusted AHI

1. INTRODUCTION

Patients with obstructive sleep apnea syndrome (OSAS) have repetitive collapse of the upper airway during sleep (American Academy of sleep medicine, 2001: ICSD, The international classification of sleep disorders, revised). The prevalence of OSAS is estimated to be 9% in women and 24% in men (Young, Peppard & Gottlieb, 2002). An apnea is a cessation of airflow at the nostrils and mouth lasting at least 10 seconds, a hypopnea an episode of shallow breathing (airflow reduced by at least 50%) lasting at least 10 seconds associated with an oxygen desaturation. The apnea-hypopnea index (AHI) refers to the number of apneic plus hypopneic episodes per hour of sleep. OSAS is classified as mild (AHI of 5-15/h), moderate (AHI of 15-30/h), and severe (AHI > 30/h) (Young et al., 2002).

The OSAS goes together with arterial hypertension what can cause cardio- and cerebrovascular illnesses like myocardium infarct or apoplexy (Eckmayr, Lang, Leitner, Hochreiter, Kolb & Flasch, 1999; Morrell, Finn, Kim, Peppard, Badr & Young, 2000; Schulz, Olschewski, Grimminger & Seeger, 2000). The apneas and hypopneas lead to a decrease in oxygen saturation of the blood, to an increase in the carbon dioxide saturation, and to arousals, which disturb in particular the deep sleep and the REM sleep and which fragment sleep (Aloia, Arnedt, Davis, Riggs & Byrd, 2004a; Rouleau, Decary, Chicoine & Montplaisir, 2002). The disturbed sleep and the decreased oxygen saturation of OSAS patients can lead to neuropsychological deficits (Aloia et al., 2004a; Decary, Rouleau & Montplaisir, 2000; Staub & Tschopp, 2009) and therefore increase the risk of accidents (Findley, Unverzagt, Guchu, Fabrizio, Buckner & Suratt, 1995; Finking & Weber, 2001; Young, Peppard & Gottlieb, 2002). Deficits in attention capacity (Bedard, Montplaisir, Malo, Richer & Rouleau, 1993; Greenberg, Watson & Deptula, 1987; Naegele, Pepin, Levy, Bonnet, Pellat & Feuerstein, 1998) and in memory functions (Bedard et al., 1993; Berry et al., 1990; Naegele et al., 1998; Salorio, White, Piccirillo, Duntley & Uhles, 2002) are reported.

An OSAS can be reduced at most by weight loss; otherwise the therapy must be applied in perpetuity every night. Without therapy the symptoms appear immediately again (Kribbs et al., 1993). The standard therapy of OSAS is the therapy with continuous positive airway pressure (CPAP). Therapy compliance is the number of hours per night during which the therapy is applied (in h/n). Poor compliance on CPAP therapy is a well known problem in OSAS patients (Aloia, Arnedt, Riggs, Hecht & Borrelli, 2004b; Karrer, Rothe, Ryckx & Keller, 2000): Published CPAP compliance data are as poor as 3.1 h/n (Aloia, Stanchina, Arnedt, Malhotra & Millman, 2005), and more than a third stop CPAP therapy definitely (Doherty, Kiely, Swan

& McNicholas, 2005; Karrer et al., 2000). Attention capacity (Bedard et al., 1993; Engleman, Kingshott, Wraith, Mackay, Deary & Douglas, 1999; Jokic, Klimaszewski, Crossley, Sridhar & Fitzpatrick, 1999; Naegele et al., 1998; Valencia-Flores, Bliwise, Guilleminault, Cilveti & Clerk, 1996) and memory functions (Bedard et al., 1993; Borak, Cieslicki & Koziej, 1996; Naegele et al., 1998) improve on CPAP therapy. However, looking at those results, repetition effect has hardly been considered. Additionally, no difference in neuropsychological performance between patients treated with effective CPAP and placebo are reported (Barbe et al., 2001; Barnes et al., 2004; Henke, Grady & Kuna, 2001), and significant worse results of OSAS patients on CPAP therapy compared to healthy subjects (Bedard et al., 1993; Staub & Tschopp, 2009). Because of these inconsistent results regarding CPAP effects, more studies are needed including neuropsychological performance and sleep quality (Saunamäki & Jehkonen, 2007; Staub & Tschopp, 2009).

Decary et al. (2000) proposed a test battery to assess cognitive functions of OSAS patients. OSAS patients performed some of those tests in Rouleau et al. (2002). Three of those tests were chosen to evaluate the effects of CPAP therapy (Staub & Tschopp, 2009): the Concentration Endurance Test (d2-Test), the Rey-Osterrieth Complex Figure Test (ROCFT), and the Logical Memory Test (of the Wechsler Memory Scale, revised; LMT). Additionally, the Paced Auditory Serial Addition Test (PASAT) was performed in the study of Staub & Tschopp (2009) as in Castronovo et al. (2009). The application of the PASAT in OSAS patients is already described in the review of Beebe et al. (2003).

Horstmann (2004) studied the influence of sleep on memory functions also with the ROCFT and the LMT but the OSAS patients on CPAP therapy were taken as controls without brain damage. To better understand the deficits regarding neuropsychological performance of OSAS patients, more detailed research is needed (Beebe et al., 2003).

Different studies tried to evaluate brain activation of OSAS patients during neuropsychological tests. The patients showed different or increased activation patterns compared to healthy controls during a working-memory task during functional magnetic resonance imaging in Archbold et al. (2009) and in Castronovo et al. (2009) because of neural compensation but decreased activation in Ayalon et al. (2009) and in Thomas et al. (2005).

Aloia et al. (2010) recommended continuing CPAP therapy, even if compliance is poorer than 3 h/n, but he does not discuss alternative therapies. Because of the listed consequential diseases of OSAS, good compliance and therapeutic efficacy are very important. Therefore, a profound assessment of alternative therapies is needed. The following alternative therapies exist: the avoidance of the supine position, the mandibular device, surgical options, or the Velumount® palatal device.

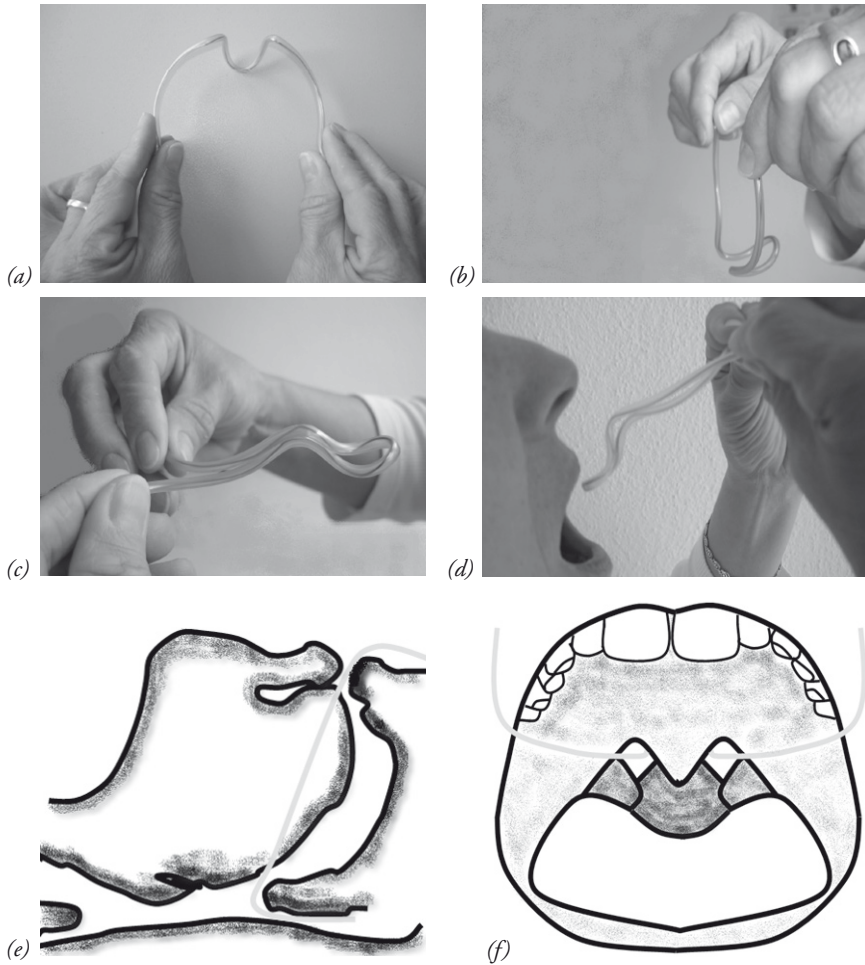


Figure 1. Insertion and operation mode of the Velumount® palatal device:

- (a) The patient holds the ends of the Velumount® palatal device between index fingers and thumbs. The arc is turned away from the patient.
- (b) The patient turns the ends outwards and the arc down (without changing the contact section between ends and fingers/thumbs).
- (c) He turns the ends away and the arc to the face.
- (d) He inserts the arc till the thumbs touch the corners of the mouth. Afterwards he closes the lips (without gritting his teeth). If he turns the ends first outwards and then up, the arc is positioned behind the velum.
- (e) Sagittal view of the operation mode of the Velumount® palatal device.
- (f) Frontal view of the operation mode of the Velumount® palatal device.

A common device to avoid the supine position (e.g. a special rucksack or a T-shirt) effectively treats patients with position dependent OSAS (Jokic et al., 1999; Finking & Weber, 2001; Maurer, Stuck, Hein, Verse & Hörmann, 2003): the AHI of more than 50% of the OSAS patients is reduced by at least 50% in lateral position compared to supine position (Oksenberg, Silverberg, Arons & Radwan, 1997; Richard, Kox, den Herder, Laman, van Tinteren & de Vries, 2006; Schäfer, 1996). The mandibular advancement device can prevent pharyngeal airway closure by pushing forward the base of the tongue together with the mandible (Lim, Lasserson, Fleetham & Wright, 2006; Marklund, Stenlund & Franklin, 2004; Vecchierini et al., 2008). Definitive changes of the airway tissue are made by surgical interventions (Ceylan et al., 2009; Robinson, Chia, Carney, Chawla, Harris & Esterman, 2009).

The Velumount® palatal device (Figure 1) is a plasticized wire which advances the soft palate opening the retropalatal space. It was developed a few years ago by A. Wyss, Switzerland. It is an effective treatment of OSAS (Tschop, Thomaser & Staub, 2009): apnea-hypopnea index (AHI), Epworth Sleepiness Scale (ESS), the subjective snoring assessment, and the average esophageal pressure were significantly reduced.

In the present study, the effects of the Velumount® device on breathing parameters, blood pressure, general well-being, and neuropsychological performance were compared for the first time to the effects of CPAP therapy.

2. METHODS

2.1. Subjects

At the Cantonal Hospital of Liestal, 18 OSAS patients (men, mean age: 60.8 years, SD: 9.2) on CPAP therapy were involved in the study. The conditions for study participation were the following: native AHI > 10/h, good acceptance of CPAP therapy with a compliance of at least 3 h/n (data taken from CPAP report), tolerance of the Velumount® device, no history of head injury, encephalitis, cerebral ischemia, and alcohol or drug abuse. Several local pneumologists established diagnosis of OSAS and titrated CPAP therapy at least 6 weeks ago (Table 1). The patients were asked to use the Velumount® device for 6 weeks instead of CPAP therapy.

Table 1. Results of the respiratory polygraphy, of the body mass index, of the blood pressure measurement, of the questionnaires, and of the neuropsychological tests

	NATIVE ^a	ON CPAP THERAPY	WITH VELUMOUNT
AHI (/h) ^b	34.6 (20.9)	8.6 (5.0)	19.1 (14.2) **
Compliance adjusted AHI (/h) ^b		15.5 (8.1)	19.6 (14.0)
Average oxygen saturation (%) ^b	93.1 (3.0) ^o	95.2 (1.3)	93.9 (2.0) **
Body mass index (kg/m ²)	28.6 (4.6)	28.5 (3.8)	28.5 (3.9)
Systolic pressure (mmHg)	138.8 (14.1) ^{oo}	141.7 (12.7) ^c	129.5 (18.6) ^c *
Diastolic pressure (mmHg)	86.8 (10.8) ^{oo}	88.6 (7.2) ^c	84.7 (9.6) ^c
ESS (0-24)	8.2 (4.9)	5.6 (3.4)	5.7 (3.0)
Snoring index (1-10) ^d	7.6 (2.6)	2.0 (2.0)	3.8 (2.2) *
Subjective sleep quality (1-10)	5.7 (2.6)	6.7 (2.2)	7.4 (1.6)
Number of side effects	–	4.3 (1.8)	1.2 (1.3) ***
Therapy satisfaction (1-10)	–	5.6 (1.3)	8.2 (1.6) **
Compliance (h/night)	–	5.7 (1.3)	7.0 (1.0) **
Compliance (%)	–	76.4 (19.0)	96.1 (6.9) **
Attention capacity ^e	–	46.4 (12.9)	53.4 (11.1) **
Paced Auditory Serial Addition Test	–	40.1 (18.5)	50.3 (18.5) **
Concentration Endurance Test	–	52.7 (10.2)	56.4 (9.0)
Memory of facts ^e	–	47.0 (13.4)	65.1 (12.1) ***
Rey-Osterrieth Complex Figure Test	–	48.3 (11.2)	65.4 (17.1) ***
Logical Memory Test	–	45.7 (18.5)	64.9 (13.3) ***

Note: Difference between CPAP therapy and Velumount[®] device: * significant between-group difference $p < 0.05$; ** significant between-group difference $p < 0.01$; *** significant between-group difference $p \leq 0.001$.

^a Data from sleep laboratory reports of the cooperating clinics before onset of CPAP therapy:

^o Native oxygen saturation was recorded in only 15 patients.

^{oo} Native blood pressure was recorded in only 12 patients.

^b In the current study, the patients were selected according to CPAP efficacy, tolerance, and compliance. The selection can lead to weighted results.

^c N = 17: blood pressure data of one patient was excluded from the study because of new medication.

^d N = 13: 5 patients are sleeping alone.

^e N = 15: 3 patients did not repeat the neuropsychological tests. The influence of the repetition effect has to be considered.

2.2. Procedure

There were two test sessions with an interval of 6 weeks, the first on CPAP therapy, the second with the Velumount® device. At both test sessions, the patients completed questionnaires and performed neuropsychological tests. Afterwards, body mass index (BMI) was registered, blood pressure was measured, and respiratory polygraphy was performed (by SOMNOcheck, Weinmann). Following the study, the individual therapy procedure was discussed in a medical consultation.

2.3. Respiratory polygraphy, body mass index, and blood pressure measurement

Respiratory polygraphy was recorded sleeping at home on CPAP therapy and 6 weeks later with the Velumount® device measuring respiratory airflow, respiratory effort (abdominal and thoracic respiration by piezo belt), snoring, body position, heart rate, and transcutaneous blood oxygen saturation by pulse oximetry. Respiratory polygrams were scored manually according to the international classification of sleep disorders (ICSD, 2001). Weight was registered and blood pressure was measured using the Riva-Rocci method.

2.4. Questionnaires

The patients had to complete the following questionnaires assessing their general well-being on CPAP therapy and with the Velumount® device: Epworth Sleepiness Scale (ESS), a visual analogue scale for snoring (1-10, 1 meaning no snoring and 10 meaning very intensive snoring), a visual analogue scale for sleep quality (1-10, 1 meaning very bad sleep quality and 10 meaning very good sleep quality), a visual analogue scale for their satisfaction with treatment (1-10, 1 meaning not content at all and 10 meaning very content), and questions about side effects (how many and what kind of side effects).

The compliance with the Velumount® device was diarized: every morning the patients had to note how many hours they had slept at all and how many hours with the Velumount® device. The results are given both in h/n and in percentage of total sleep time.

2.5. Neuropsychological tests

As in Staub and Tschopp (2009), the neuropsychological test battery was designed to measure attention capacity and memory of facts. The tests were

performed following the instructions of Spreen and Strauss (1998). The Paced Auditory Serial Addition Test (PASAT) and the Concentration Endurance Test (d2-Test) were taken as tests of attention capacity. In the PASAT, numbers are presented orally in intervals (2.4, 2.0, 1.6, and 1.2 seconds: 4 runs with 61 numbers each). The subjects have to add every number to the one that immediately precedes it. The d2-Test consists of 14 lines with 47 letters (either d or p) each. The letters are carrying 1 to 4 dashes. The targets are the letters d with two dashes. The subjects have to mark the targets within 20 seconds per line.

To assess memory of facts, the Rey-Osterrieth Complex Figure Test (ROCFT) and the Logical Memory Test (of the Wechsler Memory Scale, revised; LMT) were used. In the ROCFT (second night: with the Taylor Figure), the subjects had to draw the figure three times. The first time, they had to copy it. Afterwards they had to draw it by heart (two free recalls; the second time after a distraction time of 30 minutes). Copying the figures, the subjects knew about the free recall. The second free recall was taken as the result. The maximum score was 36 points (as in Spreen & Strauss, 1998). In the LMT, the subjects heard two German stories acoustically presented by the computer. They had to repeat the two stories twice: the first time immediately, the second time after a distraction time of five minutes. The second evening, two other stories were presented. The second recall was taken as the result. The highest possible score of each German story was 23 points (and not 25 as in the Wechsler Memory Scale, revised; Lezak, 1995).

The correct answers of each test were expressed as percentage of the total possible correct answers. Answers expressed as percentage allows to compare different tests: a comparison of different kinds of tests within one neuropsychological capacity (e.g. different memory tests), or a comparison of different neuropsychological capacities (e.g. memory functions and attention capacity). The answers expressed as percentage therefore also facilitates a comparison of different papers. The mean of the percentages of the two tests of attention capacity and the mean of the percentages of the two tests of memory of facts were calculated, as the two tests of each category were weighted equally.

2.6. Statistics

SPSS for Windows (Version 11.0) was used for statistical analyses, assessing homogeneity of variance by the Levene test, normal distribution by the Shapiro-Wilk test.

Parameters with homogeneity and normal distribution: The significance (p, two-tailed) of the therapeutic effects was assessed by the paired t-test (t_a).

Parameters without homogeneity or normal distribution: The significance (p, two-tailed) was assessed by the Wilcoxon Signed Ranks test (Z).

Correlations were calculated by Pearson's method (in homogeneous and normal distributed parameters; R_p), or by Spearman's method (R_s).

Additionally, the treatment success with regard to AHI was estimated according to the Sher criteria (AHI \leq 20/h and an AHI reduction of at least 50%, compared to the native AHI; Sher et al., 1996). Regarding snoring, a snoring index \leq 3 was considered as socially not disturbing and therefore as a therapeutic success (as in Tschopp et al., 2009).

2.7. Comparative study factors

A unimodal comparison of different OSAS treatment options will always be incomplete and may lead to unjustified conclusions. Only consideration of all major aspects in sleep medicine will fulfill the criteria for a well-balanced evaluation. The proposed criteria for comparing different treatment modalities in OSAS are listed in Table 2 and may help in scoring the quality of published data.

When the AHI of different therapies are compared, compliance data should always be considered. The newly proposed compliance adjusted AHI is calculated according to the following formula:

$$\text{AHI}_{\text{compliance adjusted}} = \frac{(\text{hours}_{\text{sleep without therapy}} * \text{AHI}_{\text{native}} + \text{hours}_{\text{sleep with therapy}} * \text{AHI}_{\text{with therapy}})}{\text{hours}_{\text{total sleep time}}}$$

This aspect is interesting particularly in patients who are treated operatively, since their compliance has to be considered as 100%, but also in patients with poor compliance with any other therapy.

The treatments should be compared in an unselected patient population. However, in the present study only OSAS patients with good tolerance and compliance of CPAP therapy were asked to participate in the study. The tolerance of the Velumount® device was also an inclusion criterion. Therefore, one patient who did not tolerate the Velumount® device was not included.

Table 2. Comparative study factors

	CONSIDERED IN THE ACTUAL STUDY
Unselected patient population	–
AHI (/h)	+
Compliance adjusted AHI (/h)	+
Average oxygen saturation (%)	+
Objective sleep quality:	
Sleep stages (min and %)	–
Sleep efficiency (%)	–
Arousal index (/h)	–
Body mass index (kg/m ²)	+
Systolic blood pressure (mmHg)	+
Diastolic blood pressure (mmHg)	+
Daytime sleepiness (e.g. ESS)	+
Subjective scoring of snoring (by bed partner; 1-10)	+
Subjective sleep quality (1-10)	+
Number of side effects	+
Therapy satisfaction (1-10)	+
Compliance (h/night)	+
Compliance (% of total sleep time)	+
Neuropsychological performance (%)	+

Note: Factors which should be considered for the comparison of different treatment modalities of OSAS. The present work is already scored according to the proposed criteria.

3. RESULTS

The results of the respiratory polygraphy, of the BMI, of the blood pressure measurement, of the questionnaires, and of the neuropsychological tests are listed in Table 1.

3.1. Respiratory polygraphy, body mass index, and blood pressure measurement

The AHI was significantly lower ($Z = -2.639$, $p = 0.008$) and mean oxygen saturation was significantly higher ($Z = -3.119$, $p = 0.002$) on CPAP therapy than with the Velumount® device. According to the Sher criteria, CPAP therapy was effective in 16 of these patients with good CPAP acceptance, the Velumount® device in 8 patients. This result is relativized by the compliance adjusted AHI, since the difference was not significant ($Z = -1.394$, $p = 0.163$) and CPAP therapy was effective in 6 patients and the Velumount® device in 8 patients according to the Sher criteria.

There was no change in BMI within the short period of 6 weeks between the two evaluation sessions ($t_a(17) = 0.244$, $p = 0.810$). Blood pressure before onset of CPAP therapy was noted in only 12 patients in the medical records, and there was a remark about borderline blood pressure values in the medical record of a further patient. This patient's blood pressure on CPAP therapy was 186/118 mmHg, demanding new hypertension medication. Therefore, his data was excluded from the study. In the other 17 patients, systolic blood pressure decreased significantly with the Velumount® device compared to CPAP therapy ($Z = -2.229$, $p = 0.026$), whereas there was a decrease tendency regarding diastolic blood pressure ($t_a(16) = 1.658$, $p = 0.117$).

In the first session, there was a significant negative correlation between BMI and oxygen saturation ($R_S = 0.586$, $p = 0.013$). *In the second session*, there was a significant correlation between BMI and AHI ($R_S = 0.666$, $p = 0.003$) and a significant negative correlation between BMI and oxygen saturation ($R_S = -0.659$, $p = 0.003$). AHI significantly negatively correlated with oxygen saturation ($R_S = -0.595$, $p = 0.009$). Compliance adjusted AHI significantly correlated with AHI ($R_S = 0.975$, $p < 0.001$), BMI ($R_S = 0.596$, $p = 0.009$), and negatively with oxygen saturation ($R_S = -0.581$, $p = 0.011$).

3.2. Questionnaires

There was no significant difference between ESS on CPAP therapy and with the Velumount® device ($t_a(17) = -0.102$, $p = 0.920$). Regarding snoring, no data were available in 5 of the patients because they were sleeping alone. Snoring was socially disturbing in 11 of the other 13 patients without therapy, still disturbing in 2 patients on CPAP therapy, and in 4 patients with the Velumount® device. The therapeutic means differed significantly ($Z = -2.113$, $p = 0.035$). Sleep quality tended to improve with the Velumount® device ($Z = -1.895$, $p = 0.058$). With the Velumount® device, the number of side effects decreased significantly ($Z = -3.635$, $p < 0.001$). The side effects are listed in Table 3.

Table 3. All side effects and their occurrence

	NUMBER OF PATIENTS REPORTING THE SIDE EFFECT
<i>All side effects of CPAP therapy</i>	
Nose dryness	5
Swollen nose mucosa	2
Nasal congestion	2
Rhinorrhea	1
Chronic rhinitis	4
Epistaxis	2
Mouth dryness	13
Cough	2
Aerophagy	1
Compression pain on the face	7
Mask leak	1
Sweating under the mask	2
Otalgia, Tinnitus	2
Impeded falling asleep	2
Increased number of awakenings during the night	4
Early awakening in the morning	6
Impeded expiration	2
Decrease in intimacy	8
Additional organization when traveling	3
Disturbing factor: CPAP noise	4
Disturbing factor: Foreign body	2
<i>All side effects of the Velumount® device</i>	
Gag reflex	4
Palatal pain	3
Irritated palatal mucosa	2
Dryness of the mucosa	5
Compression pain	2
Swallowing pain	1
Increased number of awakenings during the night	2
Early awakening in the morning	1
Decrease in intimacy*	3

* According to the patients "less than on CPAP therapy".

Therapy satisfaction ($Z = -3.103$, $p = 0.002$), compliance in h/n ($t_a(17) = -3.449$, $p = 0.003$), and compliance in percentage of total sleep time ($Z = -3.103$, $p = 0.002$) increased significantly with the Velumount® device.

In the first session, there was a significant correlation between subjective sleep quality and therapy satisfaction ($R_S = 0.547$, $p = 0.019$), and a significant negative correlation between subjective sleep quality and BMI ($R_P = -0.635$, $p = 0.005$). Age significantly negatively correlated with ESS ($R_P = -0.615$, $p = 0.007$). Additionally, there was a significant negative correlation between diastolic blood pressure and compliance (in h/n: $R_S = 0.527$, $p = 0.030$; in percentage: $R_S = -0.651$, $p = 0.005$). Compliance adjusted AHI significantly negatively correlated with the compliance (in h/n: $R_S = -0.568$, $p = 0.014$; in percentage: $R_S = -0.618$, $p = 0.006$) but not with AHI ($R_S = 0.340$, $p = 0.167$).

In the second session, there was a significant correlation between ESS and the number of side effects ($R_S = 0.534$, $p = 0.022$), and a significant negative correlation between snoring and therapy satisfaction ($R_S = -0.679$, $p = 0.011$). Age significantly negatively correlated with ESS ($R_P = -0.589$, $p = 0.010$).

Between compliance in h/n and compliance in percentage of total sleep time, there was only a significant correlation in the first session (1st session: $R_S = 0.837$, $p < 0.001$; 2nd session: $R_S = 0.326$, $p = 0.187$).

3.3. Results of neuropsychological tests

The results of attention capacity ($Z = -2.840$, $p = 0.005$) and of the memory of facts ($Z = -3.408$, $p = 0.001$) with the Velumount® device were significantly better than the results on CPAP therapy. The improvement from session 1 to session 2 was +7.0% (SD: 7.1) in attention capacity and +18.2% (SD: 10.0) in memory of facts. However, the repetition effect has to be considered.

In the first session, there was a significant correlation between ESS and results of attention capacity ($R_S = 0.706$, $p = 0.003$), and a significant negative correlation between age and results of memory of facts ($R_S = -0.520$, $p = 0.047$).

In the second session, there was a significant correlation between ESS and results of attention capacity ($R_S = 0.678$, $p = 0.006$). The results of memory of facts were significantly correlated with oxygen saturation ($R_S = 0.528$, $p = 0.043$).

In addition to all these results may be mentioned that following the study, 2 patients alternately used CPAP therapy and the Velumount® device (each time the nose was congested or irritated, and on vacation). Seven patients continued CPAP therapy. Nine patients abandoned CPAP therapy. Three of them used only the Velumount® device, one combined the Velu-

mount® device with a device to avoid the supine position (a special rucksack), and one used the Velumount® device together with a chin bandage to hold the mouth closed. Three patients used only the rucksack device to avoid the supine position because of position dependent OSAS. One patient decided for surgery.

4. DISCUSSION

In the literature, no comparative study between CPAP therapy and the Velumount® palatal device has been published. In the present study, the following data were collected: (a) physiological results of respiratory polygraphy, BMI, and blood pressure measurement, (b) questionnaire answers, and (c) neuropsychological results.

Average AHI and oxygen saturation of these patients were significantly better on CPAP therapy than with the Velumount® device. The Velumount® device reduced the AHI similar to CPAP therapy in some OSAS patients. In other patients, however, CPAP therapy was superior to the Velumount® device. Comparing the results between CPAP therapy and the Velumount® device, it has to be kept in mind that all the study patients were experienced CPAP users and the therapeutic efficacy was approved by a sleep laboratory. The Velumount® device, on the other hand, was new for all these patients.

Compliance is a major factor to be considered when evaluating or comparing therapeutic modalities. Compliance adjusted AHI is an instrument to assess the therapeutic effects more detailed. It was calculated as mentioned above. While CPAP therapy was effective according to the Sher criteria in 16 patients regarding AHI, it was effective in only 6 patients regarding compliance adjusted AHI. Using the Velumount® device, the Sher criteria were fulfilled for AHI in 8 patients and for compliance adjusted AHI also in 8 patients. The compliance adjusted AHI did not differ significantly between CPAP therapy and the Velumount® device.

As expected, CPAP compliance in the present patient population was better than that reported in the literature (Aloia et al., 2005) because one inclusion criteria for this study was good acceptance of CPAP therapy. The CPAP industry is developing devices for better tolerance. However, the present-day compliance is not better than in previous studies of recent years. In an actual study about the effects of CPAP therapy, only 20 of 40 patients used the device at least 4 h/n and 5 nights/week (Saunamäki et al., 2010).

CPAP compliance is normally given in h/n. However, individual sleep time may vary considerably from 5 h/n to 10 h/n (ICSD, 2001). Therefore,

individual use of therapeutic means and total individual sleep time should be considered for a more precise assessment of the acceptance of a therapy. This is achieved by the compliance given in percentage of total sleep time.

Blood pressure can decrease because of the repetition effect (Staub & Tschopp, 2009). In that comparative study between a native test session and a CPAP test session, systolic blood pressure decrease was not significant ($t_a(13) = 1.50$, $p = 0.158$). However, in the present study the decrease from the CPAP test session to the session with the Velumount® device was significant ($Z = -2.229$, $p = 0.026$). This is noteworthy and should be evaluated in further studies.

However, even if the patients of the present study slept quite well on CPAP therapy, most of them preferred the Velumount® device. Over all, the patients scored their general well-being with the Velumount® device better than on CPAP therapy. The compliance and therapy satisfaction were significantly higher with the Velumount® device than on CPAP therapy. There were highly significantly less side effects and a tendency to subjective better sleep quality. The number of side effects correlated with daytime sleepiness and therapy satisfaction significantly depended on snoring assessment and subjective sleep quality. For further evaluation of these preliminary findings, a study with polysomnography is needed to assess sleep efficiency, sleep stages, and arousal index. It has been demonstrated that sleep efficiency can decrease significantly using CPAP therapy compared to native sleep efficiency in OSAS patients (Staub & Tschopp, 2009).

Neuropsychological tests have never been performed before with OSAS patients using the Velumount® device. However, looking at the neuropsychological performance, the influence of the repetition effect has to be considered. From a previous study a repetition effect is known. The differences in neuropsychological performance between the sessions on CPAP therapy and with the Velumount® device lay within this range (Staub & Tschopp, 2009). However, because individual improvements varied, the neuropsychological performance was considered in the medical consultation following the study.

The patients of the present study did not achieve normative data in the PASAT as given in Spreen and Strauss (1998; aged: 50-69 years; $n = 30$: 54.6% correct answers over all 4 runs). In Castronovo et al. (2009), both the healthy controls (men, mean age: 42.2 years; $n = 15$) and the OSAS patients (men, mean age: 43.9 years; $n = 17$) made just a few errors (controls: 5.13; patients before CPAP therapy: 21.53; patients on CPAP therapy: 7.56). For a better comparison, the correct answers should be expressed as percentage of the total possible correct answers: with the given information, the results would be 97.9%, 91.0%, and 96.9%, respectively.

The OSAS patients in Felver-Gant et al. (2007; mean age: 52.8 years; n = 56) assessed at baseline without therapy 124 correct answers (51.7%). On CPAP therapy, patients with high adherence assessed about 136 correct answers (56.7%), patients with low adherence assessed only about 118 correct answers (49.2%). In Aloia et al. (2010), high adherers (mean age: 53.6 years; n = 95) reached 117.6 correct answers (49%) at baseline, 131.6 correct answers (54.8%) after 3 months on CPAP therapy, and 138.8 correct answers (57.8%) after 6 months on CPAP therapy. Low adherers (mean age: 50.6 years; n = 55) performed rather better in all sessions: 124.4 correct answers (51.8%) at baseline, 133.6 correct answers (55.7%) after 3 months on CPAP therapy, and 140.4 correct answers (58.5%) after 6 months on CPAP therapy. In Staub and Tschopp (2009), the OSAS patients (mean age: 52.0 years; n = 14) reached only 38.0% at baseline but 54.6% on CPAP therapy.

However, the improvements between the two sessions in the PASAT in Castronovo et al. (2009), in Felver-Gant et al. (2007), in Aloia et al. (2010), and in the present study can be explained by the repetition effect as already discussed in Spreen and Strauss (1998; referring to Gronwall, 1977), and in Staub and Tschopp (2009), where the controls (mean age: 50.6 years; n = 18) reached 60.9% in the first evening and 71.5% in the second evening. The repetition effect is discussed neither in Castronovo et al. (2009) nor in Felver-Gant et al. (2007) but they associated the improvements with CPAP therapy. Aloia et al. (2010) even stated that the significant improvements are not caused by the repetition effect but by CPAP therapy. However, there were similar improvements in all subjects independent of the state of health (patients and healthy subjects; Staub & Tschopp, 2009). The impairment of the low adherers in Felver-Gant et al. (2007) can be caused by decreased sleep efficiency on CPAP therapy (Staub & Tschopp, 2009). Felver-Gant et al. (2007) stated that further research is needed to detect deleterious effects of CPAP therapy.

In the d2-Test, the patients of the present study performed rather better than those in Staub and Tschopp (2009; baseline: 48.2%; on CPAP therapy: 53.8%) but worse than those in Jokic et al. (1999; mean age: 51 years; n = 13; baseline: 68.0%; on CPAP therapy: 77.3%). The patients in Jokic et al. (1999) achieved even rather better results than healthy persons in Spreen and Strauss (1998; men, aged: 50-59 years; n = 5: 67.5%) and in Staub and Tschopp (2009; baseline: 56.0%; repetition: 64.6%).

It is difficult to compare the results to the OSAS patients in Rouleau et al. (2002) because only the numbers of errors but neither the numbers of correct answers nor the numbers of possible answers were given (OSAS patients: mean age: 47.4 years; n = 28: 11.3 errors; controls: mean age: 47.2

years; $n = 18$: 7.4 errors). The official d2-Test actually consists of 658 letters (Spreen & Strauss; 1998). The subjects in Rouleau et al. (2002) would have reached 98.3% and 98.9%. Rouleau et al. (2002) followed the instruction of Richer et al. (1993; according to Brickenkamp's test of 1966): The test consisted of 600 letters (3 conditions, five rows with 40 characters), mathematically resulting in 98.1% and 98.8% correct answers. Naumann (2002) reported quite another result: Healthy young controls (mean age: 38.7 years; $n = 15$) only reached 72.3% correct answers. For meaningful comparisons between studies, it would be advantageous to have the performance correctly expressed as percentage of the maximum score.

The repetition effect can cause improvements also in the memory of facts, even if different figures (in the ROCFT) and different stories (in the LMT) are presented in the second session (Staub & Tschopp, 2009). Castronovo et al. (2009) used an alternative list in the Rey learning list and explained the better results again only by therapeutic effects.

In the 30-min. recall of the ROCFT, the healthy controls reached 47.2% in Spreen & Strauss (1998; aged: 50-59 years; $n = 21$) and 48.9% in Rouleau et al. (2002). However, the controls of Rouleau et al. (2002) performed rather worse than the OSAS patients (52.5%). In Twigg et al. (2010), the results are expressed as percentage of the score of the first copy. In doing so, the OSAS patients (mean age: 51 years; $n = 60$) reached 47.8% and the controls (mean age: 50 years; $n = 60$) 55.6%. In Staub and Tschopp (2009), the controls (67.7%) and the OSAS patients (67.9%) performed rather better than in the present study, also in the second evening (81.6% and 77.2%), probably because they were 10 years younger.

Comparing results of memory of facts of different papers, the participants' age of the studies has to be considered because of the significant negative correlation between age and results of memory of facts. It is not surprising that young healthy controls in Naumann (2002; mean age: 36.0 years; $n = 21$) performed rather better (61.3%; taking 23 points as the maximum) in the LMT than the controls in Rouleau et al. (2002; 40.0%; taking 25 points as the maximum), the controls in Twigg et al. (2010; 54.0%; taking 50 points as the maximum), and the controls in Staub and Tschopp (2009; 55.4%). The OSAS patients of the present study performed rather better than those in Rouleau et al. (2002) with 34.8% but similar to those in Twigg et al. (2010) with 44.0% and similar to those in Staub and Tschopp (2009) with 44.1% at baseline and 61.3% on CPAP therapy. In the crossover study of Jokic et al. (1999; taking 23 points as the maximum), the patients reached 41.3% with the positional treatment and 39.1% on CPAP therapy.

Neuropsychological testing demonstrates an important aspect of OSAS and should be considered in evaluation of different treatment modalities.

OSAS may cause irreversible brain damage and there is a residual deficit in neuropsychological performance also on optimized CPAP therapy (Bedard et al., 1993; Staub & Tschopp, 2009). The significant correlation between ESS and results of attention capacity demonstrates that the subjective assessment of sleepiness does not correspond to neuropsychological performance (Moller, Kayumov, Bulmash, Nhan & Shapiro, 2006), highlighting the importance of objective tests.

Data from this preliminary study justify further studies to compare CPAP therapy with the Velumount® device in unselected patient populations. Monitoring should be performed by polysomnography to answer questions about sleep quality (e.g. sleep efficiency, sleep stages, arousal index) and its influence on well-being and on neuropsychological performance (considering the repetition effect).

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ABBREVIATIONS

AHI	Apnea-hypopnea index
BMI	Body mass index
CPAP	Continuous positive airway pressure
d2-Test	Concentration Endurance Test
ESS	Epworth Sleepiness Scale
h/n	hours per night
ICSD	The international classification of sleep disorders, revised
LMT	Logical Memory Test (of the Wechsler Memory Scale, revised)
OSAS	Obstructive sleep apnea syndrome
PASAT	Paced Auditory Serial Addition Test
ROCFT	Rey-Osterrieth Complex Figure Test