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APAP Gerätetechnik und die Korrelation mit der Patienten-Compliance

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APAP device technology and correlation with patient compliance

Automatic positive airway pressure (APAP) devices are used in the treatment of obstructive sleep apnea (OSA) and other sleep-related respiratory disorders. These devices automatically modify respiratory pressure during therapy and are used when patients exhibit differing pressure needs throughout the night or are unable to tolerate the high levels of pressure delivered by conventional continuous PAP (CPAP) devices as well as when automatic titration of the patient is warranted. Automatic pressure modification varies greatly depending on the APAP device [1, 2, 3]. In addition, individual patients have different levels of tolerance to APAP therapy. This makes it difficult to choose the most appropriate APAP device for each patient. However, not using an APAP device when it is clinically indicated can result in pressure support treatment being discontinued as a result of non-compliance, which in turn markedly increases the risk of secondary disease [4].

The aim of this study was to determine whether it is possible to utilize technical analysis of APAP devices to predict the level of compliance with therapy in advance.

Material and methods

The study was based on computer-aided simulation of a human lung based on a mathematical model, whereby the duration of obstruction phases was fully customizable. Obstructive and central events as well as changes to respiratory stimula-

tion were simulated using the active lung and obstruction simulator (ALOSI) [5] based on normal respiratory activity with a respiratory volume of 500 ml, an inspiration-expiration ratio (I/E) of 1/1.5 and a respiratory rate (f_A) of 14 breaths per minute. The lung simulator was linked to the obstructive element (OE) via a USB connection and an analogue-to-digital converter (ADC) (■ Fig. 1). Conventional pressure sensors (HCLA0050DB) and a pneumotachometer (Rudolph 4700A) were used as pressure gauges. The system was validated for the first time in 2007 with an active electropneumatic lung simulator in Hamburg [3]. The APAP devices to be tested were connected to this lung model.

The active lung and obstruction simulator operates as a closed-loop system.

This means that if respiratory pressure is increased to a suitable level by the APAP device, no more obstructions can be generated. This is not the case with all simulators described in the literature [6, 7]. Obstructions were simulated in such a manner that they were fully treated once respiratory pressure reached 10 hPa. Central hypopnea was simulated by reducing the simulated respiratory flow by 70%. Central events were simulated by stopping respiratory stimulation completely. Changes in respiratory stimulation were realized so that when respiratory stimulation was increased, peak expiratory flow and respiratory minute volume increased by 25% compared to normal respiration and fell by 75% when respiratory stimulus was reduced. By combining individual respi-

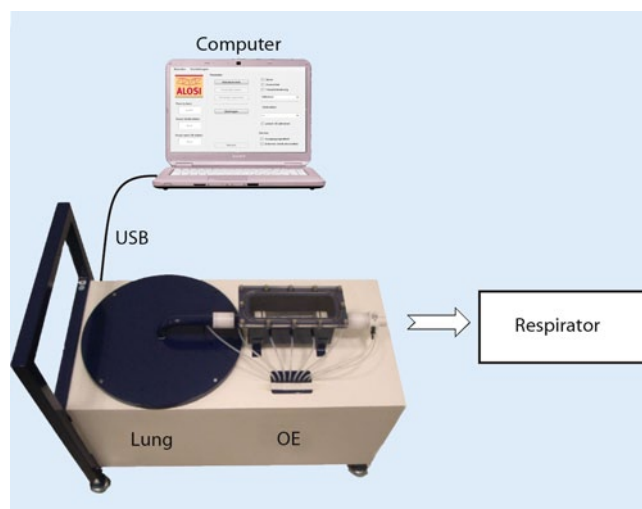


Fig. 1 ◀ Functional overview of the ALOSI set-up

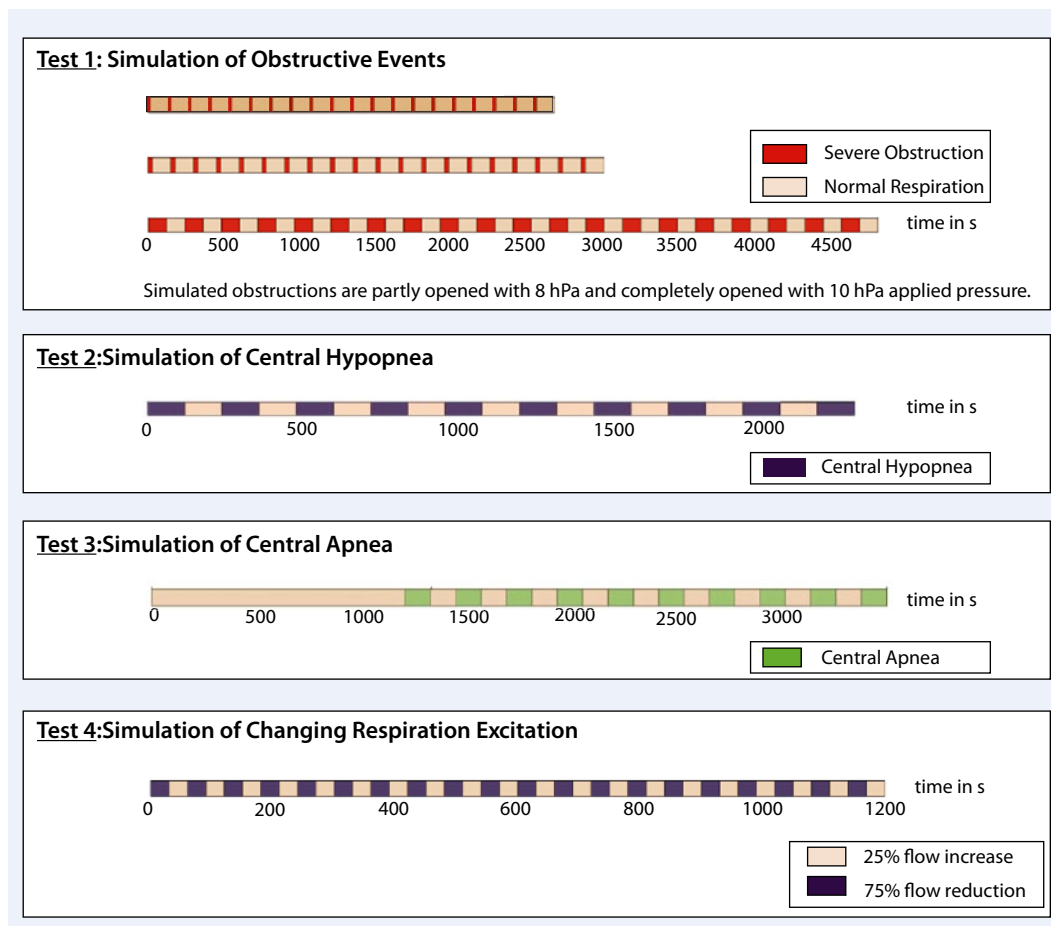


Fig. 2 ◀ The four test sequences used in the simulation

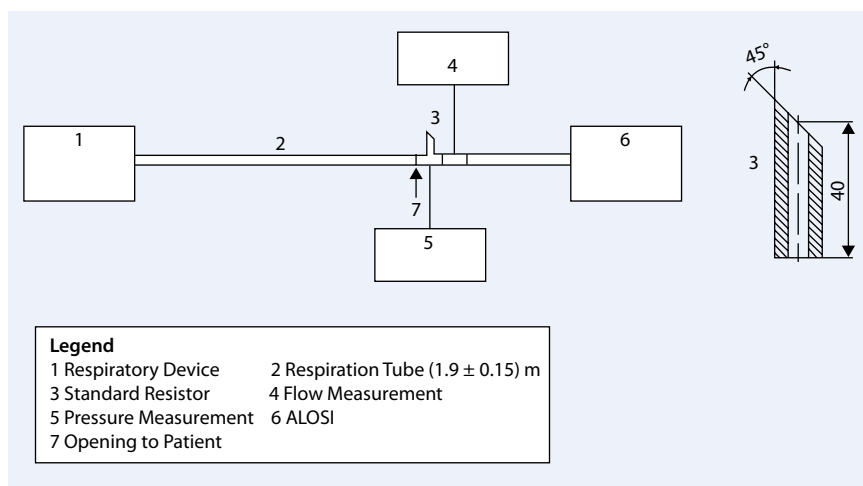


Fig. 3 ▲ Measurement protocol showing 1 respiratory device, 2 respiration tube (1.9 ± 0.15 m), 3 standard resistor, 4 flow measurement, 5 pressure measurement, 6 ALOSI and 7 opening to patient

ratory events, four tests were developed (■ Fig. 2). Test 1 assessed the control behavior of APAP devices in the presence of obstructions of varying durations (e.g. 15, 30 and 120 s). Tests 2–4 assessed APAP device behavior under conditions of simulated central hypopnea, central apnea and

changes to respiratory stimulation. Each test was preceded by a 20 min simulation period consisting of 20 min of obstruction-free respiration, allowing initialization of the APAP device. This phase is shown in ■ Fig. 2 for test 3.

The lung simulator and the four tests were used to examine the pressure modification behavior of nine commercially available APAP devices. Measurement protocols are depicted in ■ Fig. 3. The devices were restarted for each individual test. The lower pressure threshold was set at 5 hPa and the upper pressure threshold at the maximum pressure of each device (usually 20 hPa), enabling the devices to automatically modify respiratory pressure within this range. Pressure and flow were recorded using the sensors preinstalled in the ALOSI simulator. Measurement data were assessed for each test sequence.

In test 1 the number of obstructions that were opened at a therapy pressure of at least 10 hPa and to what extent respiratory pressure fell after the end of each obstruction were determined. An example of this is shown in ■ Fig. 4. The obstruction was opened after the eighth obstruction phase, and a total of 18 min: in some cases pressure reductions of 20–30% were observed in relation to minimum pressure (5 hPa). Because pressure increases

and decreases are linked, the parameters for each test sequence were scaled to the maximum factor of 10 for further usage.

In tests 2–4 it was determined whether respiratory pressure remained unchanged in the case of central hypopnea, central apnea or variable respiratory stimulation. Respiratory pressure should remain unchanged in all of these events. If a change in pressure was observed it was given a value of 0 and otherwise 10. Results were determined for each APAP device for test 1 as an average of the three test sequences and a weighted average of tests 1–4, whereby obstruction parameters were weighted more strongly than respiratory stimulation parameters (by a factor of 10) due to their relevance to APAP device pressure modification. The resulting parameters were standardized on the basis of the highest value which was set at 100%. These parameters described the pressure modification characteristics of each of the APAP devices examined. As a result an arbitrary weighting was used for these factors; however, it can be assumed that obstructive events are of a pathological nature and should therefore be weighted more strongly than central events, which could potentially be of a physiological nature. Pressure should therefore be modified after the conclusion of obstructive phases, which is how the weighting was derived.

In order to examine the medical relevance of the technical parameters, the health insurance company DAK-Gesundheit provided anonymous compliance data for over 7000 patients from across Germany who had been treated between 1 January 2010 and 31 December 2011 with one of the APAP devices tested. Given that the customers of DAK-Gesundheit represent the German population as a whole, it can be assumed on the basis of the data collection period and the number of patients that the data constituted a representative random sample that accurately depicted the population of German APAP patients. The data from DAK-Gesundheit included information on the APAP device used and whether therapy was suspended for a period of ≥ 3 months and a total usage time of < 300 h beginning from delivery of the APAP device to the patient. For each APAP device it was also determined what percentage of

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APAP device technology and correlation with patient compliance

Abstract

Question. The aim of this study was to investigate the technology of automatic positive airway pressure (APAP) devices and to determine correlations with patient compliance.

Material and methods. A computer-aided simulation of a human lung based on a mathematical model was used. Obstructive and central events, and changes in respiratory patterns were simulated using the active lung and obstruction simulator (ALOSI) and six commercially available APAP devices were tested. Correlations between technical results and real life compliance with APAP devices were determined using German health insurance data.

Results. There was considerable variation in the results between devices and with technical differences between algorithms. Individual results were used to determine technical

parameters to define the pressure modification behavior of each APAP device. There was a significant correlation between technical findings and patient compliance data.

Conclusion. This is the first study to document a link between the technological performance of APAP devices and compliance with therapy. The testing method used allowed reproducible analysis and comparison of pressure modification algorithms of APAP devices. These methods have potential usefulness for predicting patient compliance to APAP therapy before treatment is started.

Keywords

Airway obstruction · Comparative study · Computer simulation · Benchmarking, healthcare · Reproducibility of results

APAP Gerätetechnik und die Korrelation mit der Patienten-Compliance

Zusammenfassung

Fragestellung. Es wird die Korrelation zwischen der automatischen Druckregelung von APAP-Geräten und der Patienten-Compliance untersucht.

Material und Methoden. Auf Basis eines mathematischen Modells wurde die menschliche Lunge simuliert. Obstruktive und zentrale Ereignisse sowie veränderliche respiratorische Muster wurden mit Hilfe des aktiven Lungen- und Obstruktionssimulators ALOSI reproduzierbar simuliert. Sechs marktgängige APAP-Geräte wurden getestet. Korrelation zwischen technischen Ergebnissen und Patienten-Compliance-Daten der DAK-Gesundheit wurden ermittelt.

Ergebnisse. Es existieren erhebliche Unterschiede bei den Algorithmen zur automatischen Druckregelung von APAP-Geräten. Aus den individuellen Ergebnissen wurde ein technischer Parameter bestimmt, der die Druckregelung jedes APAP Geräts charakter-

isiert. Es besteht eine signifikante Korrelation zwischen dieser technischen Kennzahl und den Patienten-Compliance-Daten.

Schlussfolgerungen. Dies ist die erste Studie, die eine Verbindung zwischen der technischen Leistung von APAP-Geräten und der Patienten-Compliance dokumentiert. Das verwendete Testverfahren erlaubt die reproduzierbare Analyse und den Vergleich der Regelalgorithmen von APAP-Geräten. Diese Methode hat einen potenziellen Nutzen zur Vorhersage der Patienten-Compliance bei der APAP-Therapie vor Beginn der Behandlung.

Schlüsselwörter

Luftwegsobstruktionen · Vergleichsstudie · Computersimulation · Benchmarking, Gesundheitswesen · Reproduzierbarkeit der Ergebnisse

patients did not suspend therapy and this was defined as patient compliance. These were all the data available because German health insurance companies do not have access to more detailed patient data. To minimize statistical errors, three APAP devices that were only used by a very small number of patients each were excluded from the study.

Results

Individual tests

The results varied considerably from device to device and examples are given in **Fig. 5, 6, 7, 8, 9 and Fig. 10**, showing pressure modification in the event of obstructions in the simulation of 20 obstruc-

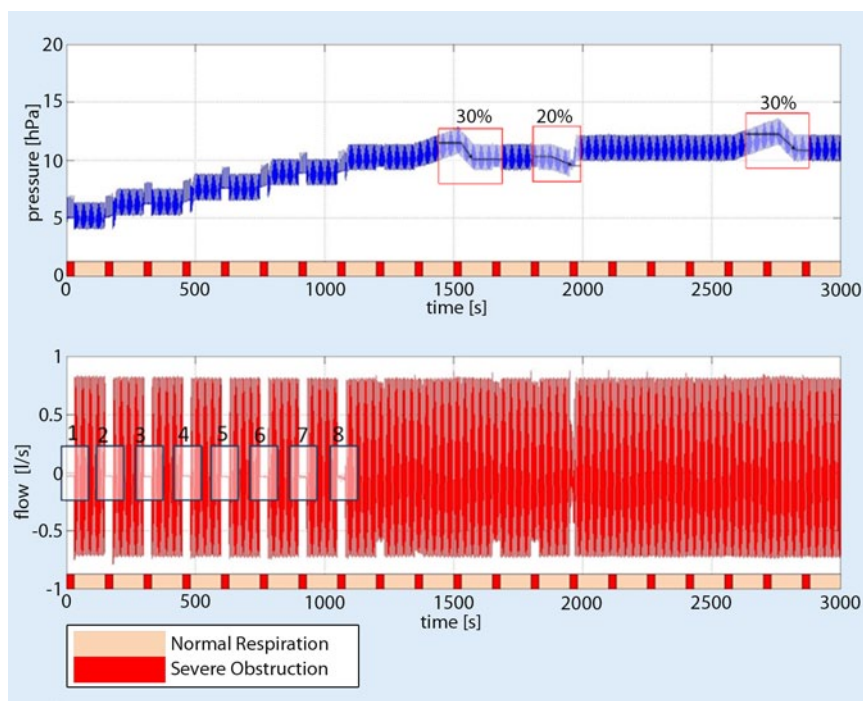


Fig. 4 ▲ Assessment of opened obstructions and pressure reductions

Tab. 1 Summary of APAP device testing results

	APAP device					
	1	2	3	4	5	6
Test 1						
Opened obstructions (n)						
Obstruction duration 15 s	20	11	8	6	4	10
Obstruction duration 30 s	20	1	1	5	12	14
Obstruction duration 120 s	20	0	0	5	0	14
Average pressure reduction after obstructions (hPa)						
Obstruction duration 15 s	0.00	0.13	0.10	0.05	0.10	0.15
Obstruction duration 30 s	0.00	0.00	0.15	0.05	0.25	0.18
Obstruction duration 120 s	0.00	0.00	0.00	0.10	0.40	0.24
Pressure variation at central hypopnea (hPa)						
Test 2	+7	+15	+11	0	0	+10
Test 3	+7	0	0	+3	+2	0
Test 4	+7	+15	+8	+9	+7	+6

APAP automatic positive airway pressure.

tions, each of a duration of 30 s (red legend), followed by non-obstructed respiration with a duration of 120 s (yellow legend) for each of the 6 APAP devices tested.

The APAP device 1 set respiratory pressure at a value of >10 hPa from the start of the simulation and increased this further to 14 hPa after 13 obstruction phases. There were no pressure reductions after obstructions (■ Fig. 5).

Device 2 increased respiratory pressure for the first time after six obstruction phases (13 min) by 1 hPa from a starting point of 5 hPa. Further pressure increases of 1–1.5 hPa occurred after 10, 13, 17 and 19 obstruction phases, meaning that respiratory pressure after 19 obstruction phases (after 45 min) allowed further obstructions to be opened. No pressure reductions took place after obstruction phases (■ Fig. 6).

Device 3 increased the respiratory pressure after the first obstruction phase and then lowered it again gradually, even during periods of obstruction. After 12 and 19 obstruction phases, respiratory pressure was again gradually increased and then lowered over a sustained period of time (■ Fig. 7).

After the second obstruction, device 4 increased the respiratory pressure after every simulated obstruction and achieved a pressure necessary to completely open the obstruction prior to 13 obstructions (after >30 min). With this device pressure reductions took place gradually after obstructions over a period of >10 min, whereby closures occurred after 17 and 18 obstruction phases (■ Fig. 8).

Device 5 increased respiratory pressure gradually during the obstruction phases, leading to complete obstruction opening after eight obstruction phases (18 min). There were isolated cases of pressure reduction. Respiratory pressure followed a distinct pattern, increasing for a short period before falling again (■ Fig. 9).

Device 6 increased pressure gradually after obstructions arose, meaning that the obstruction was fully opened after three obstruction phases and 5.5 min. Pressure reductions took place systematically at around 1 hPa within a period of 5 min, provided no further obstructions occurred. When pressure was reduced below the level necessary to open recurring obstructions (obstruction phases 9, 14 and 18), pressure was increased after the respective obstruction phase (■ Fig. 10).

When examining central hypopnea (test 2) it was found that four out of the six APAP devices examined modified respiratory pressure during therapy. Pressure increases during the test sequences varied between 7 and 5 hPa to total pressure levels of 13 or 20 hPa. During simulated central apnea (test 3), three APAP devices increased respiratory pressure by between 2 and 7 hPa. All APAP devices examined increased respiratory pressure by 6–15 hPa in the test involving simulated obstruction-free changes in respiratory stimulation (test 4). A summary of the results for tests 1–4 for all six devices in a table format is given in ■ Tab. 1.

Parameters for technical assessment

The individual results were used to determine technical parameters in order to define the pressure modification behavior of each APAP device. Using device 6 as an example, the parameters were calculated as follows: in the case of an obstruction duration of 30 s, device 6 opened 14 out of the 20 simulated obstructions (■ Fig. 10). For subsequent assessment this resulted in a scaled value of 7 out of 10. After 12 obstruction phases pressure fell by 0.3 hPa, whereas after 8 obstruction phases there was no pressure reduction. The average pressure reduction therefore equalled: $(12 \times 0.3 \text{ hPa} + 8 \times 0 \text{ hPa}) / 20 = 0.18 \text{ hPa}$. For a maximum pressure reduction of 5 hPa from the opening of an obstruction to the lowest pressure level, the pressure reduction was scaled by a factor of 10: $0.18 \text{ hPa} / 5 \text{ hPa} \times 10 = 0.36$. The assessment of obstruction opening and the average pressure reduction was then scaled by a value of 10. In the case of a test with 30 s obstructions, this resulted in an overall assessment of $(7 \times 0.36) / 10 = 0.25$. For test procedures with obstruction durations of 15 s and 120 s, assessments were carried out accordingly. A mean value was formed from the assessments of the three different test procedures. In the example used this mean value is 0.25. The reaction to changes in pressure in the case of central hypopnea, central events and variations in respiratory stimulation were valued at 0 in the event of a pressure increase and at 10 in the event of no pressure increase. For the overall assessment in tests 1–4, the result from test 1 was weighted with a factor of 10 and offset against the results from tests 2 to 4. This produced the following overall result for device 6: $(0.25 \times 10 + 0 + 10 + 0) / (10 + 1 + 1 + 1) = 0.96$.

Medical relevance

The relationships between the technical parameters in the presence of obstructions (test 1) and patient compliance for the six APAP devices studied are given in ■ Fig. 11. The diameter of the circles and the figures next to the circles correspond to the number of patients treated with each APAP device. There was a clear

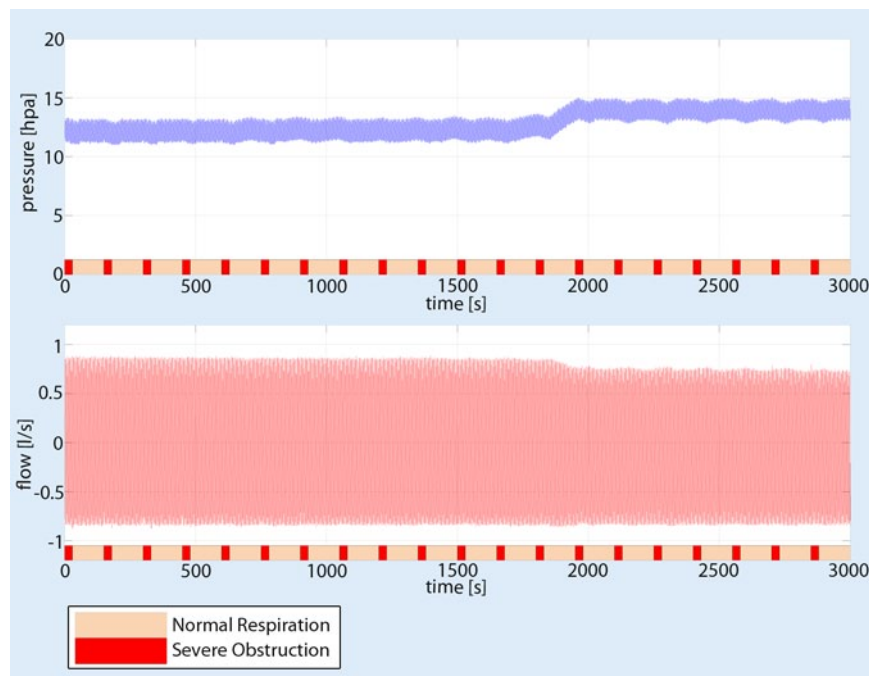


Fig. 5 ▲ Device 1: obstruction test (30 s)

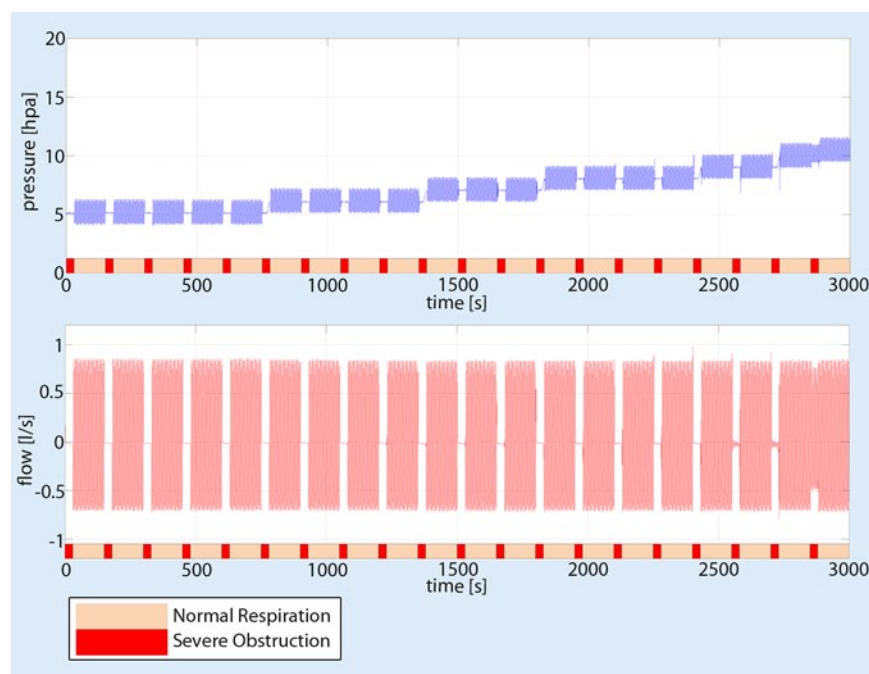


Fig. 6 ▲ Device 2: obstruction test (30 s)

correlation between the technical assessment and patient compliance. If tests 2–4 were also included in the technical assessment, the correlation coefficient for the relationship between the technical assessment and patient compliance was 0.86 (■ Fig. 12).

Discussion

This study developed testing methods to compare the technology of commercially available APAP devices. The results showed technical differences between devices and a significant correlation between technical findings and patient compliance

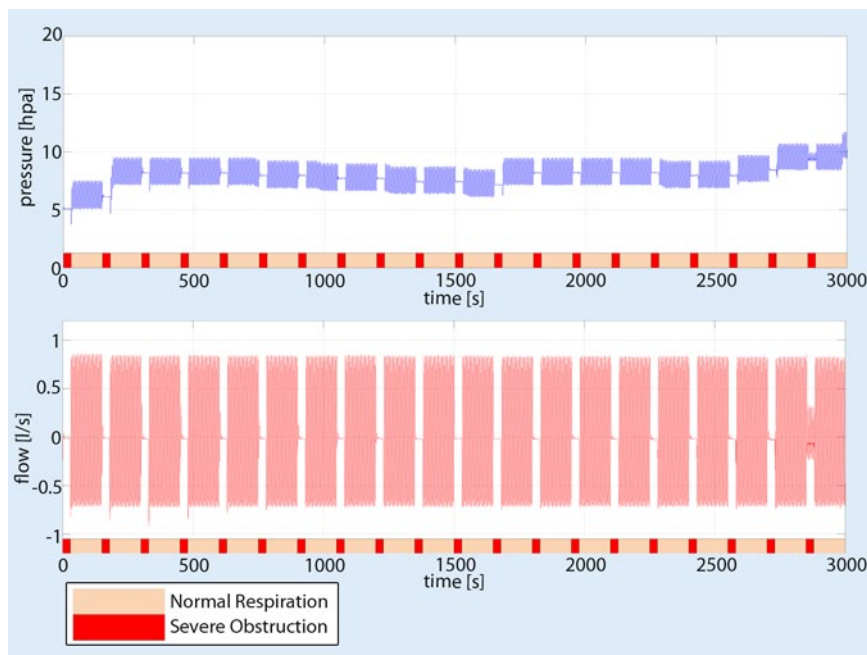


Fig. 7 ▲ Device 3: obstruction test (30 s)

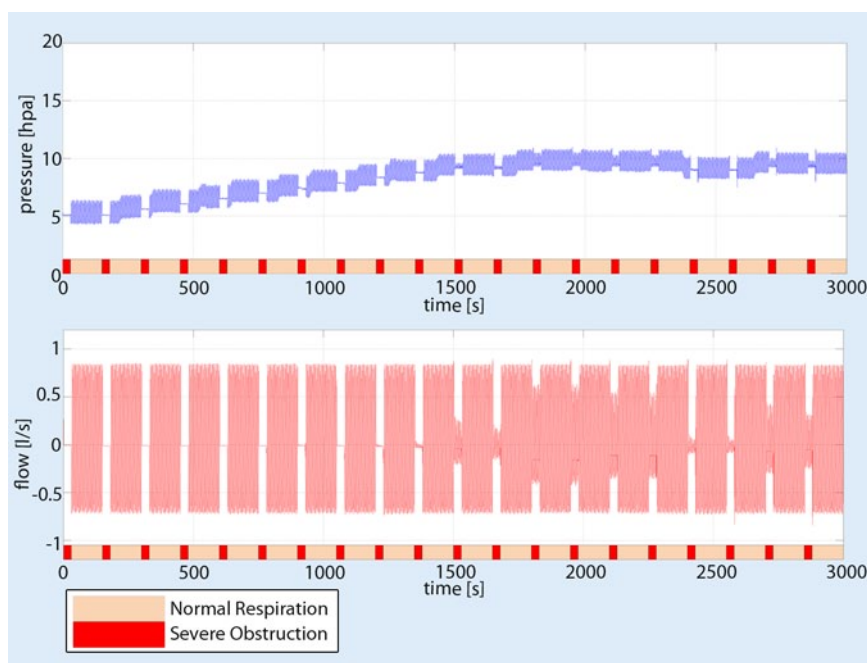


Fig. 8 ▲ Device 4: obstruction test (30 s)

data. Although there is the potential for discrepancies to occur during technical examination of devices, they were minimized in the current study by utilizing repeated tests with repeated calibration of the lung simulator. Reproducible results were delivered in all of the tests. The aim of the developed test procedures was not to simulate a standard patient, but to examine how the respective APAP device reacted to simple,

but relevant, obstruction and respiratory flow patterns. Different devices had different methods of modifying respiratory pressure in the event of obstructions: one device increased pressure at the start of therapy so that no further obstructions took place then increased pressure further and did not reduce it after obstruction phases, while others increased respiratory pressure gradually to a level necessary to open the

obstruction. All devices reduced pressure, but according to very different patterns. In general, many of the APAP devices did not appear to be very dynamic when it came to modifying pressure in the event of and following the conclusion of obstructions. In a previous APAP bench study [2] only three out of ten APAP devices tested achieved the respiratory pressure of 12 hPa necessary to overcome the obstruction within a maximum of 22 min. In contrast, all six of the APAP devices examined in the present study opened the simulated obstructions at a respiratory pressure of ≥ 10 hPa, although this only occurred within a period of up to 45 min after the first obstruction. Given that newer APAP devices were tested in the current study, it is possible that technical developments may be responsible for this pressure modification.

The APAP devices tested reacted very differently when central hypopnea and apnea were simulated. This could be the result of pressure modification strategies, as well as direct or indirect measurement of the central nature of the event, differing between devices and/or manufacturers. One notable factor was that all APAP devices modified pressure in the presence of obstruction-free changes to respiratory stimulation. One reason for this could be that the 30 s duration of the phases of modified respiratory stimulation caused the APAP devices to calculate a new baseline. All in all, there were considerable differences in reactions compared with test 1. This suggests that in comparison to the devices examined in the previous study [2], APAP technology has been developed further because this bench study was based on an open-loop lung simulator and all APAP devices examined in the study reacted identically to central and obstructive apnea.

A lung simulator cannot replace a real patient. Simulators cannot, for instance, accurately represent the central nervous system or upper airway collapse. However, lung simulators do allow reproducible testing procedures and create results that enable objective analysis and indications of real behavior during APAP therapy [7]. The parameters generated by the test results for each APAP device consisted of the results of all test phases. Multiplying pressure increase behavior with mean pressure reduction ensures that

these related parameters are jointly taken into consideration. In order to guarantee that all phases of test 1 were assessed in a uniform fashion, the results were combined to generate a mean value. The subsequent scaling of the values ensured that the results of this test were weighted more strongly than the results from tests 2 to 4 by a factor of 10. This means that the reaction of an APAP device to an obstruction is given greater significance than the device's response to central events, and that the ability of the APAP devices to treat obstructive sleep apnea under changing control pressures can be accurately analyzed.

Patient compliance with APAP therapy using the devices tested in this study was high (■ Fig. 11, 12). At between 8% and 16%, the rate of APAP therapy interruption was significantly lower than that reported previously [8]. There could be a number of reasons for this. Apart from technical factors, such as the device-related pressure modifications, factors influencing continuation with APAP therapy could include the type of mask [9] and the set-up and support provided during APAP therapy [10]. When comparing ■ Fig. 11 and ■ Fig. 12, it is evident that the obstruction parameter from test 1 had a much greater influence on the results as a result of the weighting, but that the results from tests 2 to 4 resulted in additional differentiation. The correlation between central events and patient compliance was less pronounced in tests 2–4. This suggests that device pressure modification in response to obstructions has a greater influence on patient compliance. It is also clear that the correlation between efficient pressure increase in the event of obstructions and modified pressure reduction in the postobstruction phase leads to greater patient compliance.

There are a number of other factors, apart from pressure modification that could contribute to a patient terminating APAP therapy. Determining the role of these additional factors is something that would be good to include in the design of future APAP compliance studies.

Conclusion

The testing method applied in this study allows the reproducible analysis and comparison of pressure modifica-

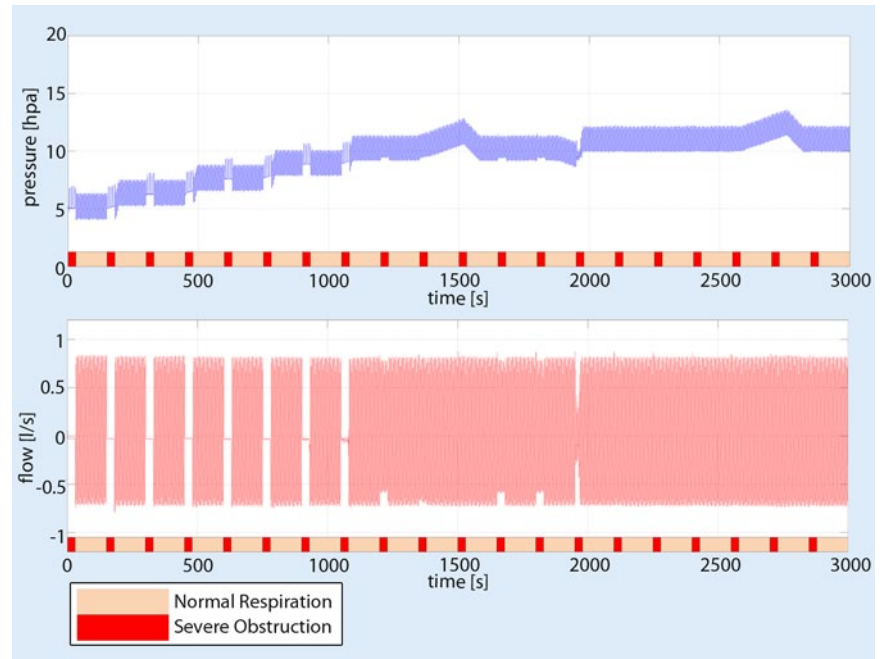


Fig. 9 ▲ Device 5: obstruction test (30 s)

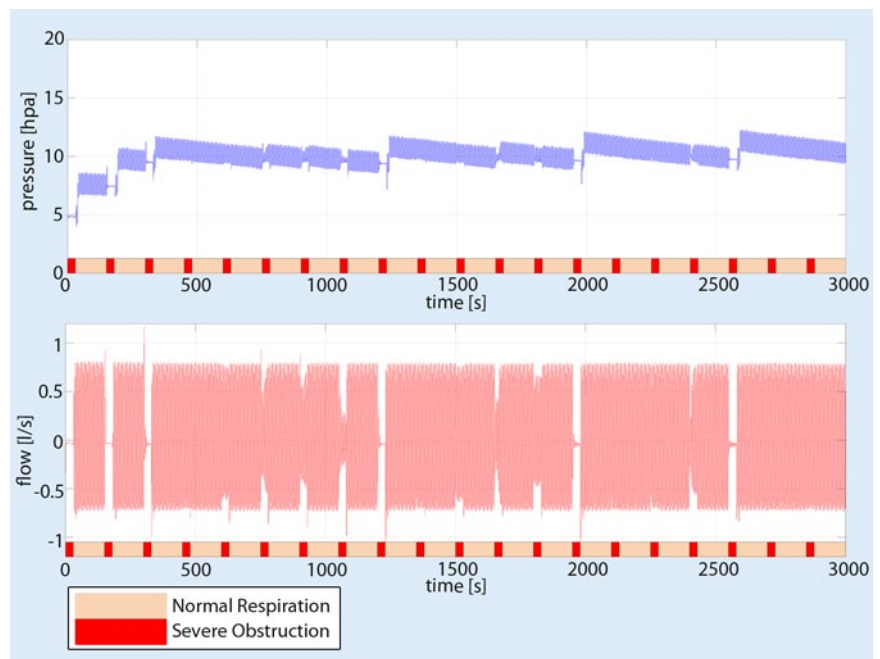


Fig. 10 ▲ Device 6: obstruction test (30 s)

tion algorithms of APAP devices. In addition, the testing methods could be used to predict patient compliance for each APAP device before therapy is started. In particular, the results of the individual tests allow a clear and comparable overview of the automatic pressure modification characteristics for each APAP device. Such analysis would make it easi-

er to select the APAP device associated with the greatest chance of therapy success. Therefore, application of pretreatment testing could considerably reduce the number of cases of incorrect therapy, therapy termination and thus secondary disease caused by untreated OSA.

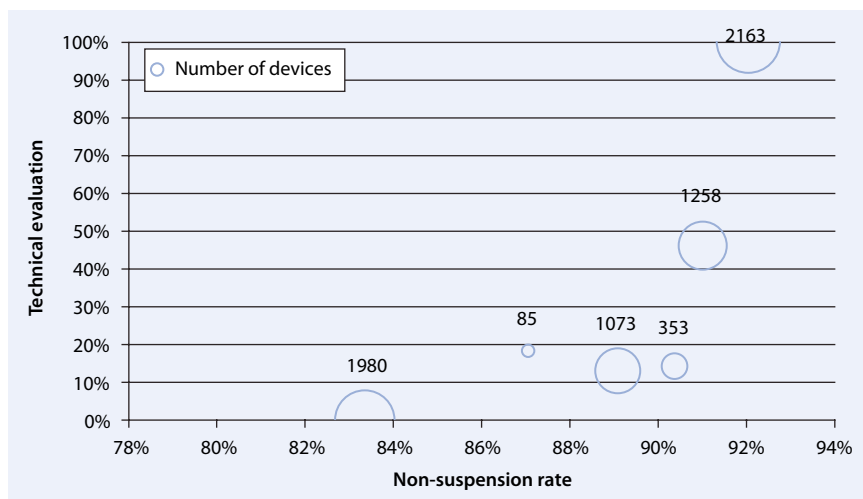


Fig. 11 ▲ Technical assessment (test 1) and compliance

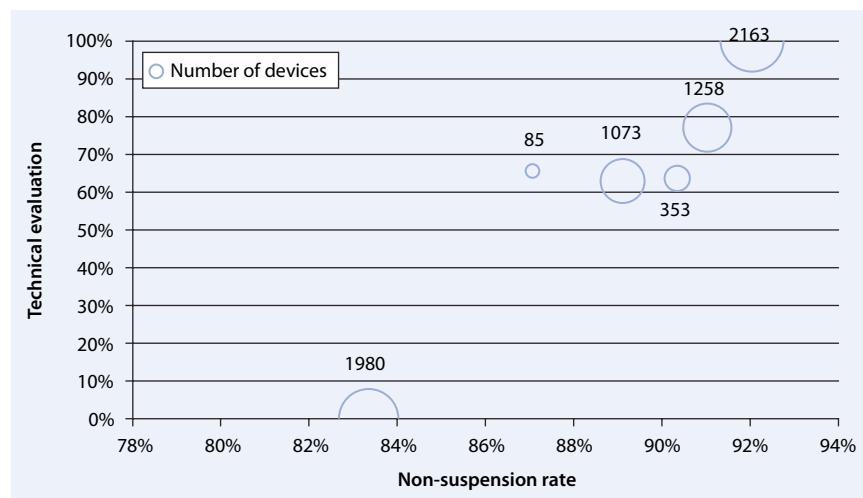


Fig. 12 ▲ Technical assessment (tests 1–4) and compliance

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Compliance with ethical guidelines

Conflict of interest. T. Netzel, H. Hein and Y. Hein state that there are no conflicts of interest.

The accompanying manuscript does not include studies on humans or animals.

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