

Test Bench for Pressure Calibration of Continuous Positive Airway Pressure (CPAP) Device for Sleep Apnea Applications

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Abstract

Aim of this study was the experimental characterization of a CPAP (Continuous Positive Airway Pressure) device used for the treatment Obstructive Sleep Apnea Syndrome (OSAS). In particular, the airflow vs. pressure characteristic for devices with different operating hours was obtained with a test bench able to simulate different obstructive levels. The study has confirmed the influence of operating hours on this characteristic, in particular, it has been observed that increasing this parameter value, it is necessary an effective pressure increase to ensure the same airflow to the patient.

This may suggest that the pressure sensors inside the CPAP may lose their calibration and therefore that a periodic check and calibration would be required, even though the device is declared as a self-calibrating.

Keywords: Automatic positive airway pressure device, sleep apnea syndrome, upper airway obstruction, Continuous Positive Airway Pressure CPAP, titration

INTRODUCTION

In this paper, an experimental study of *Continuous Positive Airway Pressure* (CPAP) devices for the treatment of Obstructive Sleep Apnea Syndrome (OSAS) is presented.

The obstructive apnea is a physical condition characterized by 5 or more apnea episode in one sleep hour (apnea index) or by a number of apnea and hypopnea bigger than 10 in one sleep hour (apnea/hypopnea index). The apnea is a phenomenon that causes a 10 seconds breath airflow break caused by a transient airways obstruction, mostly during the night. While in the hypopnea, there is a 30% reduction of airflow for at least 10 seconds in respirations. Both causes obviously a decrease in oxygen saturation.

The partial or total obstruction of the airways (apnea) OSAS is caused by a non-equilibrium of the forces, which avoid the involvement of the first airways during the inhalation (contraction of the pharyngeal dilating muscles), and the forces

which favor it (intrathoracic negative pressure). This phenomenon is favored by the presence of soft tissue in excess often caused, but not always, by a surplus of adipose tissue.

After an apnea event, the airway natural ventilation is only possible with a micro-awakening or a real awakening, causing a fragmented and not resting sleep.

Among the sleep respiratory diseases, the OSAS is the more common and studied [1-3], in fact in western countries it involves more than 4% of male and 2% of woman adults respectively. Its incidence is steadily increasing, in fact, epidemiological data show an incidence in the male population above 60 years old of about 20%.

The drowsiness daytime is also considered a social problem, in fact many people affected by the OSAS pathology tend not to have a good rest and tend to fall asleep while driving, provoking many road accidents.

For these reasons an early and correct diagnosis is very important. This is possible thanks to the polysomnography, a diagnostic exam that consists of a night recording of different parameters like:

- blood oxygen saturation,
- heart rate,
- presence/absence of apnea of air flow through the mouth and nose,
- presence/absence of chest and abdominal movements,
- position held by the subject during sleep,
- presence/absence of snoring during sleep.

After this evaluation, it is possible to make a “personalization” of the airway pressure device for home use. This process, titration phase, could be made manually or by automatic devices.

An expert medical technician makes the manual titration phase consisting in a pressure regulation during the night sleep monitoring in hospital. While the titration with automatic device is made using an auxiliary self-calibrating device named auto-CPAP or APAP.

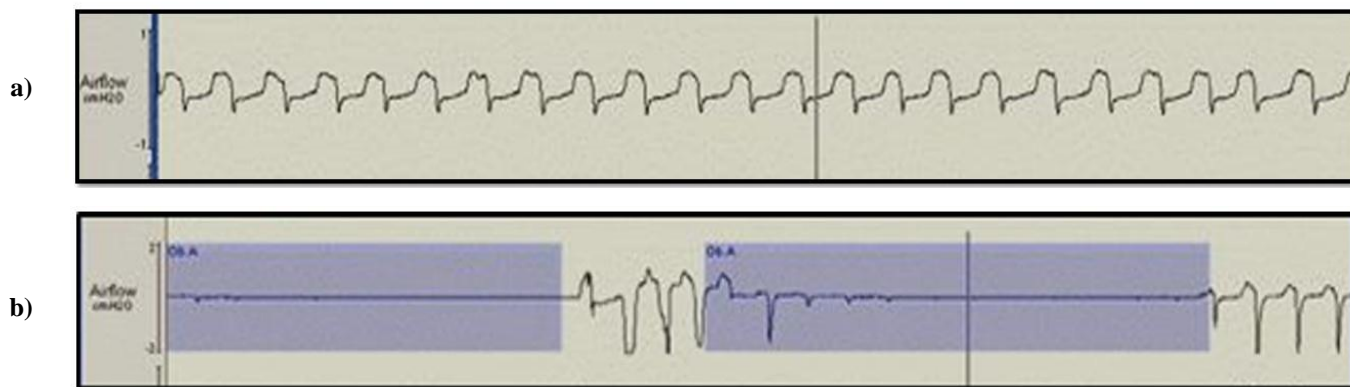
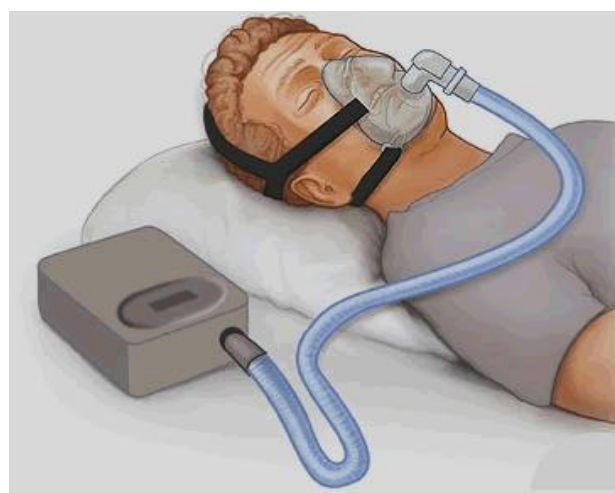


Figure 1: Polysomnography a) healthy subject, b) subject with OSAS

This titration consists in identifying the minimum effective operating pressure (pressure at the 90^o percentile, corresponding to the pressure that is able to eliminate the 90% of sleep apneas) and the corresponding airflow value able to keep the airways open. Usually the minimum effective pressure is between 4 and 20 cmH₂O and it is set on the personal CPAP device.

Figure 1 shows the airway outline obtained with a polysomnography of: a) healthy and b) pathological (with OSAS) subject respectively. It is possible to note that in a) the airflow has a regular behavior while in b) the airflow in some phase (inside the cyan squares) is practically equal to zero, indicating the presence of apnea.



(a)

The CPAP device

The most used therapeutic treatment for OSAS is a treatment with CPAP device that allows counteracting the tendency of the upper airways to collapse and reduces the apnea episodes restoring a physiological respiratory pattern.

Figure 2a shows a picture that represents the patient use during the sleep phase. Thanks to a mask, the airflow reaches the respiratory airways; this mask guarantees the comfort and reduces the physical disturbance (irritation and nasal congestion). To avoid the patient to breathe his own produced carbon dioxide, small-calibrated slits are present in the connection part between the tube and the mask (see figure 2b).



(b)

Figure 2: a) Application of CPAP device, b) Particular of the connection part



Figure 3: Example of CPAP device

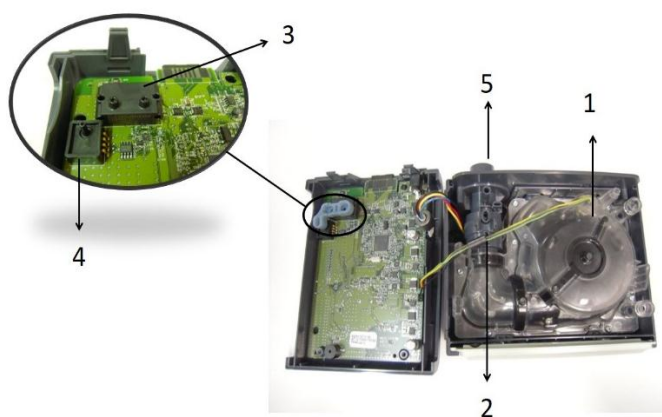


Figure 4: Internal view of a CPAP device (example)

Figure 3 shows an example of commercial CPAP device. It is able to make two type of therapies:

- APAP therapy: the device is used at home by the patient for one week for the detection of all airway parameters, to record the abnormal events and evaluate the effective pressure.
- CPAP therapy: when the effective pressure has been individuated the hospital technician makes the set-up of the device, fixing the effective pressure value. The device can now be used for home therapy.

The device is able to take over, not only the obstructive apnea, but also some secondary phenomena like the airflow limitation, the hypopnea and the snoring.

The operating principle of the CPAP can be described referring to an example of CPAP show in figure 4. A turbine (1) accelerates the airflow, taken from the environment and filtered to avoid impurities intake, it is able to regulate the pressure during treatment. Downstream of the turbine, a shaped duct (2) is connected, upstream and downstream, to a differential pressure sensor (3), which is used to calculate the flow rate required for ventilation thanks to mathematical algorithms properly implemented and stored into the electronic board.

Downstream of the element (2), another pressure sensor allows measuring the device output pressure (4).

A microcontroller acquires and compares, in real time, the pressure signal from the differential sensor (3) and the exit pressure (4) to make the closed loop control.

The CPAP individuates an apnea condition when the flow, calculated thanks to the differential pressure, is lower than a fixed threshold and it supplies a certain value of airflow corresponding to the fixed effective pressure.

CPAP device' experimental tests

The purpose of the investigation illustrated in this paper is to evaluate the influence of the time of use (working hours) on the threshold effective pressure value of CPAP devices. The study is inserted in a wide activity research about medical and innovative devices [5-14] made inside the Mechanical and Aerospace Engineering Department of Politecnico di Torino.

Various researchers investigated on the CPAP devices operation both in vivo [17] and with test benches simulating the real working [15, 16]. These studies point out the importance of increasing the event detection algorithms accuracy in order to better detect the effective pressure level versus time. Moreover periodic calibration procedure of pressure sensors inside the device itself seems to be a parameter not considered by researches [1-6]. Also for some commercial devices, in fact, the calibration procedure is not expected, while usually pressure sensors for various applications decrease their accuracy during their use and require periodic calibration.

The experimental tests carried out in this study aim to simulate the real operating conditions. A pneumatic circuit was made, to allow reproducing, by in vitro experiments, different physical situations, from the physiological one to the pathological conditions with various levels of respiratory tract obstruction.

Figure 5 shows the airflow passage (black arrows) through the different components of the circuit: an example of CPAP device (1), the connection (2) with small-calibrated slits (see figure 2b) opened or closed, the duct (3) that reproduces the airways and a flowmeter (4) to measure the airflow.

For simplicity in this study, the airways have been considered, as a rigid duct corresponding to the trachea. Different gradually descending dimensions of duct (3) simulate the physiological dimension of the trachea of a healthy subject and of different patients. Analyzing the physiological average data [18] it is possible to consider an internal diameter of human trachea equal to 16 mm and an airflow value of 0.25 L/s for a healthy subject and without obstruction disease. While when a hypopnea is present, an airflow equal to 0.15 L/s can be considered and with an obstructive apnea the airflow is reduced at 0.05 L/s. These last two conditions correspond to a duct with a diameter of 12 mm and 7 mm respectively (Table 1).

Table 1

	A (physiological)	B (hypopnea)	C (apnea)
Diameter [mm]	16	12	7
Airflow [L/s]	0.25	0.15	0.05

Table 2

	Device 1	Device 2	Device 3	Device 4	Device 5
Operation time [h]	0	250	1450	2950	4270
Average period of use	new	1 month	2 months	> 1 year	> 2 years

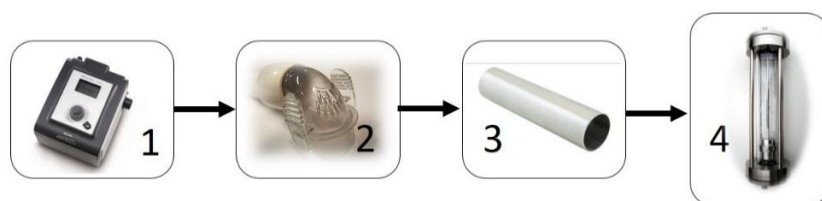


Figure 5: Test circuit layout

Five equal commercial CPAP have been considered for the experimental tests. They have different number of operation hours, corresponding to different periods of use (see Table 2). This period is calculated considering an average use of the device of 7 hour/day.

To verify the repeatability and the absence of hysteresis of each experimental test, three measurements have been made to obtain the average value and the standard deviation. The average curves are presented in figure 6 to 9; for each plots the standard deviation is not presented because the value is always less than 0.5 L/min.

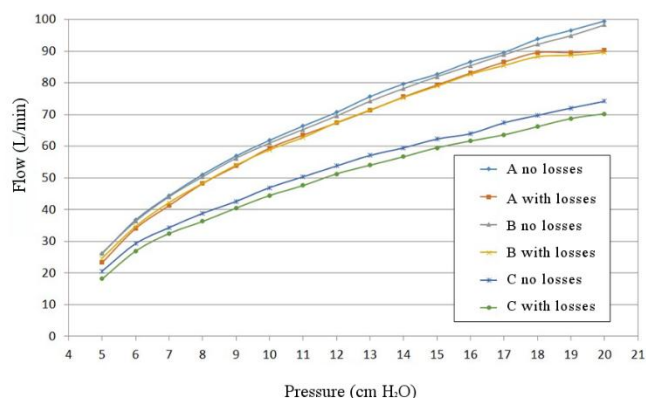


Figure 6: Airflow vs. pressure – Device 1, different obstruction levels, connection with small-calibrated opened slits (with losses) or closed (no losses)

Figure 6 shows the airflow vs. pressure behavior for the device 1 for different levels of obstruction (A, B, C), considering the connection with small-calibrated opened slits (with losses) or closed (no losses).

Figures 7 and 8 show the airflow vs. pressure behaviour for the different devices in case of physiological (A) and apnea condition (C) with small-calibrated opened slits (with losses) that corresponds to the real operation of the CPAP.

These figures represent the good and worst condition. It is possible to observe that, for both cases, curves are changing when the number of operating hours (from device 1 to device 5) increases. In particular, it is necessary to increase the effective pressure to guarantee the same airflow to the patient.

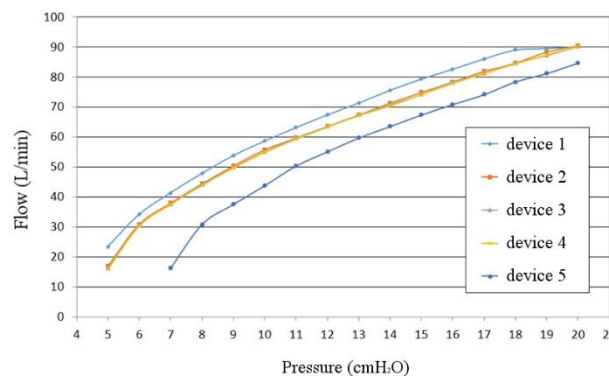


Figure 7: Airflow vs. pressure – different devices and physiological airway (A)

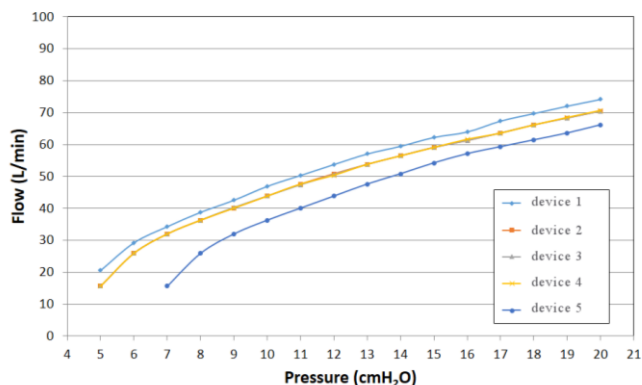


Figure 8: Airflow vs. pressure – different devices and obstructive apnea (C)

CONCLUSIONS

A bench to test CPAP with different obstructive levels has been made. Preliminary tests with same type of CPAP having different operating hours have been carried out to compare their airflow characteristics. The study has confirmed the influence of operating hours on the characteristic airflow - pressure for the considered type of CPAP. In particular, it has been observed that, increasing the number of operating hours, it is necessary an effective pressure increase to ensure the same airflow to the patient.

This may suggest that the pressure sensors inside the CPAP may lose their calibration and therefore that a periodic check and calibration would be required, even though the device is declared as a self-calibrating.

The continuation of this study could include an improvement of the test bench in order to test and characterize some devices in a fatigue condition, periodically verifying the airflow vs. pressure behavior. This could be useful to evaluate the pressure calibration during the whole life of the CPAP. Another interesting investigation could be the addition to the bench of a secondary circuit including other pressure sensors to make a redundant measurement.

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