

## Review Article

# EPAP Devices Optipillows, Bongo Rx, and Theravent: Flow Resistance and The Pressures They Generate

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**Abstract**

Theravent and Optipillows are expiratory resistance devices indicated for snoring, and Bongo Rx is indicated for mild to moderate obstructive sleep apnea. The goal of this study is to compare side by side the resistance of the three devices and the pressure that they generate. The devices' resistance was evaluated using steady air flow at 100 ml/sec or simulated breathing. We calculated the device's resistance either at a flow rate of 100 ml/sec or as the slope of the pressure-flow curve. The pressure generated during expiration with simulated breathing was also measured. The study shows that the resistances of Theravent and Bongo Rx were identical regardless how they were calculated. The resistance of Optipillows was equivalent to Theravent and Bongo Rx when the side vent was between 50 to 75% closed. Likewise, with simulated breathing, the pressure generated during expiration was identical in Theravent and Bongo Rx, and was comparable to the expiratory pressure with Optipillows when the side vent was closed between 50 to 75%. In conclusion, the three expiratory resistance devices had comparable resistance and generate comparable expiratory pressure. Despite the fact that some devices are cleared for snoring and some for obstructive sleep apnea, any of these three devices can work for either condition. The healthcare provider can recommend whichever is most accessible to the patient. The adjustable resistance on the Optipillows provides an option for the patient to select low resistance while adapting to the device.

**ABBREVIATIONS**

CPAP-continuous positive airway pressure, EPAP- expiratory positive airway pressure, OSA-obstructive sleep apnea

**BRIEF SUMMARY**

Some EPAP devices are intended to treat snoring while others are intended for obstructive sleep apnea. It is not clear if the intended use is determined by the level of their expiratory resistance or the pressure they generate during expiration. This study shows that despite the fact that some devices are cleared by the FDA for snoring and some for obstructive sleep apnea, the resistance of the three devices are comparable and therefore can be used for either condition. The physician can decide if any of these devices are suitable for their patients.

**INTRODUCTION**

The pathophysiology of obstructive sleep apnea can be explained by the collapse of upper airways secondary to the slight negative pressure that develops during inspiration. During sleep, the upper airway muscles relax, but the airway passage remains open enough to allow air to flow in most individuals. In some individuals, the upper airway collapses, causing airflow obstruction. Partial obstruction of the upper airway causes

snoring noise, and complete block causes total cessation of airflow called obstructive sleep apnea (OSA). The preferred treatment for snoring or obstructive sleep apnea is continuous positive airway pressure (CPAP). The mechanism of preventing OSA is the stenting action by the positive pressure in the upper airway [1]. The positive pressure stabilizes the upper airway, preventing collapse during inspiration. Expiratory positive airway pressure (EPAP) devices have recently been shown to be safe and effective in many patients with snoring and obstructive sleep apnea [2-6]. They have been considered a welcome addition to the options available for patient care [7-9]. It is unclear why such devices are not always as effective in all patients as CPAP [2, 10]. Previously we discussed the possible reasons why CPAP is superior to EPAP [11]. We emphasized that the primary difference is that with CPAP, the pressure remains positive during the entire breathing cycle eliminating any potential collapse of the upper airway. With EPAP, the pressure is positive only during the expiration and remains near zero or becomes slightly negative during inspiration, allowing upper airway collapse in some users.

EPAP devices allow the user to inhale with ease, but during expiration, the device's resistance causes the upper airway pressure to become positive during exhalation. The device's effectiveness depends on their resistance and the pressure they generate. Information is sometimes provided about the expiratory

resistance. Measurements in clinical trials while using EPAP devices have shown peak nasal pressure during expiration ranges from 5 to 20 cmH<sub>2</sub>O [12]. It is not clear what causes such a wide range in pressure, considering that the resistance is fixed. The device's resistance is usually reported as the pressure developed with a steady flow of 100 ml/sec, and the ratio of pressure to flow is reported in cmH<sub>2</sub>O/L/sec. Provent (Ventus Medical, Belmont, CA) was described to provide resistance values of 50 cmH<sub>2</sub>O/l/ sec [2-5]. In contrast, Theravent (Ventus Medical, Belmont, CA) is reported to have lower resistance values of 30 cmH<sub>2</sub>O/L/sec [13]. The resistance of Bongo Rx (Airavant Medical, Deerfield Beach, FL) was only reported in an abstract [14]. Optipillows EPAP mask (Cpapnea Medical, Phoenix, AZ) has an adjustable expiratory side vent that provides resistance values between 2 to 75 cmH<sub>2</sub>O/L/ sec [15]. Some of the EPAP devices are cleared for treatment of snoring (Theravent and Optipillows EPAP Mask), and some are

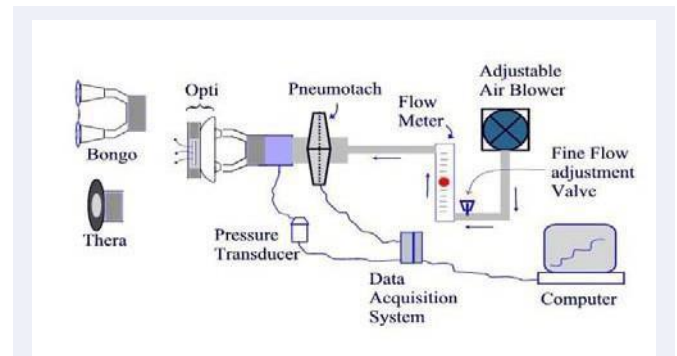
cleared for the treatment of obstructive sleep apnea (Bongo Rx), however it is not clear if the indication for use is related to the pressure generated by the device. This fact can be confusing for clinicians when deciding if the EPAP device is appropriate for their patients. This study aims at characterizing the resistance of three EPAP devices, Optipillows EPAP mask, Bongo Rx, and Theravent, and the pressure that they generate, side by side, using the identical equipment calibrations and procedures.

## MATERIAL AND METHODS

### Comparison of the EPAP devices using Steady unidirectional flow

Figure 1 shows the experimental setup used to compare the three devices with a steady flow. The design included an air blower with adjustable settings (ResMed S9 CPAP machine). The air from the blower passed through a tube flowmeter with a floating ball (Dwyer Instruments VFB-68, Michigan City, IN) to use for calibration of the flow meter and verify the accuracy of the flow rate measurement. The pressure was measured from a side port utilizing a pressure transducer (Grass Instruments, Warwick, RI). The pressure transducer was calibrated by applying a static pressure from the CPAP machine. A Pneumotach (Biopac Systems, Airflow Transducer TSD 117, Goleta, CA) was included in the setup to allow continuous recording of the flow rate. The pressure transducer and flow rate signals were fed through a data acquisition system (Biopac Systems UM100A, Goleta, CA), displayed on a computer monitor, and stored on a computer. Verification of the pressure and flow rate measurements were done repeatedly during the experiment. The EPAP devices were prepared to be easily connected to the airflow system (Figure 1). The Optipillows EPAP Mask and Bongo Rx were connected to the airflow system via a wide bore Y-connector. Theravent (regular strength) was adhered onto an adaptor's surface and was connected to the airflow system. The Optipillows EPAP Mask was tested with the side vent 50% and 75% closed. These two settings were selected because they were easy to estimate and identify. The measurements were made using two levels of flow rates, 100 and 200 ml/sec, which are within the range of expiratory flow rate in human adults.

After completing calibration and verification of zero levels, one EPAP device was connected, and the flow was set at 100



**Figure 1** The experimental setup used to measure the pressure with the steady unidirectional flow of 100 or 200 ml/sec in the three EPAP devices. The adjustable air blower was a CPAP machine.

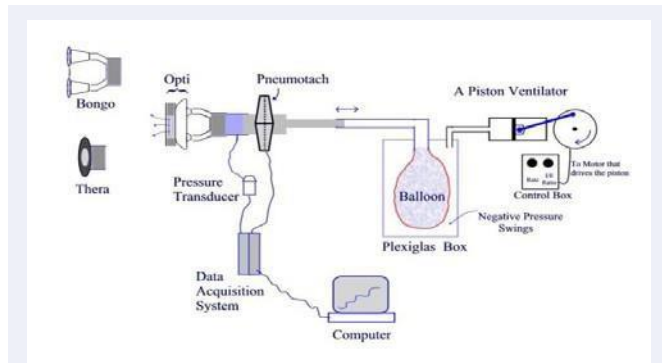
ml/sec, then at 200 ml/sec. Adequate time was allowed for the pressure to change and reach a steady level at each flow rate. The EPAP device was switched, and the measurements were repeated for the other EPAP devices in random order. Theravent and Bongo Rx had a fixed-resistance and were measured once with the two flow rates. This measurement was repeated 12 times for each of the EPAP devices in random order.

The resistance of each device was calculated as the ratio of pressure to the recorded flow. Furthermore, the resistance was also calculated using the pressure-flow curve slope between 100 and 200 ml/sec (A more reliable value for assessing resistance). The results are shown as mean±SD, and differences in pressures and resistances were compared using multi-variance analysis with post hoc comparisons of selected pairs using the Bonferroni test. A p-value of less than 0.05 was considered significant.

### Comparison of the EPAP devices using simulated breathing

In this series of experiments, we measured the expiratory pressure generated by the EPAP devices using a similar setup to simulate breathing. The setup is described in (Figure 2) and was designed to mimic normal breathing at rest, generating a known tidal volume of air moving in and out of the EPAP device (200 or 400 ml), with a frequency of breathing (15 per min), and standard flow rate. We utilized a Plexiglas chamber in which a special respiratory breathing balloon was suspended. A Harvard respirator (Harvard Apparatus Model 613 Dual-Phase respirator) was connected to the chamber to create negative pressure swings causing inflation and deflation of the balloon. The swings in the pressure provided a flow of air in and out of the balloon of 200 or 400 ml. The EPAP devices were tested in random order. The data were recorded and stored on the computer.

After completing the calibration of the flow and pressure sensors, the respirator was started to simulate breathing. The EPAP devices were prepared as above and connected to the system in random order. The Optipillows EPAP Mask was tested as before with the side vent 50% and 75% closed. The first EPAP was tested and then replaced with another device, and the measurements were repeated. The measurements were repeated 12 times on random EPAP samples.



**Figure 2** Setup used to measure the pressure and flow during simulated breathing with 200 ml or 400 ml.

**RESULTS**

Table 1 shows the devices' calculated resistance at 100 and 200 ml/sec as well as the slope of the pressure-flow curve between 100 and 200 ml/sec. At 100 ml/sec, Theravent and Bongo Rx's resistances were practically identical (12.76+1.05 and 13.21+1.29 cmH<sub>2</sub>O/L/sec). Likewise, the calculated resistance at 200 ml/sec was also identical for Theravent and Bongo Rx but differed from the values calculated at 100 ml/sec. The resistance at 100 ml/sec is usually reported for other EPAP devices. The resistance of Optipillows with the side vent 50 % closed was smaller than the resistance of Theravent and Bongo (p < 0.05) but with 75% closed, the resistance was much larger (p < 0.05). The slope of the pressure-flow curve was also identical for Theravent and Bongo. The slope for Optipillows with the side vent 50% closed was smaller than Theravent and Bongo Rx but was much larger when 75% closed (p<0.05). The slopes are displayed in a graphical format in Figure 3.

As Figure 3 shows, the slopes were identical for Theravent and Bongo Rx (44.19±1.32 and 45.36±1.15 cmH<sub>2</sub>O/L/sec). In comparison, the slope with Optipillows was 30.66±2.06 and 76.56±4.43 cmH<sub>2</sub>O/L/sec with the side vent 50% and 75% closed, respectively.

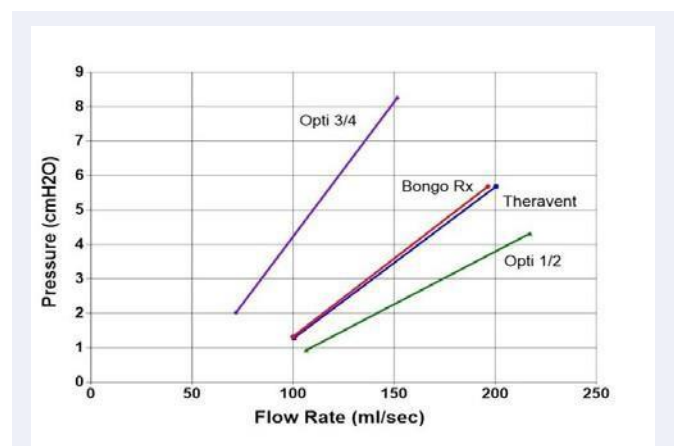
Figure 4 shows typical tracings of pressure and flow during simulated breathing with 400 ml tidal volume. One breathing cycle (inspiration and expiration) with each of the three EPAP devices is shown. The tracing of each cycle was cut and pasted to prepare the figure. As expected, the pressure during expiration became positive during the entire exhalation period with all three devices (Figure 4). The flow rate with the different devices was set by the respirator, and was not affected by the device. The pressure wave with Bongo Rx and with Theravent looked identical. Optipillows with the side vent 50 and 75% closed produced pressure waves slightly smaller and larger than the other two devices, respectively. The pressure during inspiration remained near zero in all three devices suggesting that inspiratory resistance is minimal for all three devices. The average peak expiratory pressures during breathing with small (200 ml) and large tidal volume (400 ml) are shown in Figure 5. Peak expiratory pressure was identical in Theravent and Bongo Rx; 3.86+0.17 and 3.75+0.18 cmH<sub>2</sub>O during breathing at low volume, respectively (left panel). Optipillows produced peak pressures of 2.32+0.11 and 8.19+0.77 cmH<sub>2</sub>O during breathing

with low volume with the side vent 50 and 75% closed. The peak pressure was larger for all devices at the higher tidal volumes, but the differences were consistent with breathing at low tidal volume: 12.91+0.43 and 12.99+0.43 cmH<sub>2</sub>O for Theravent and Bongo Rx, respectively. In comparison, the Optipillows produced and 8.03+0.29 and 22.16+1.59 cmH<sub>2</sub>O with the side vent 50% and 75% closed, respectively.

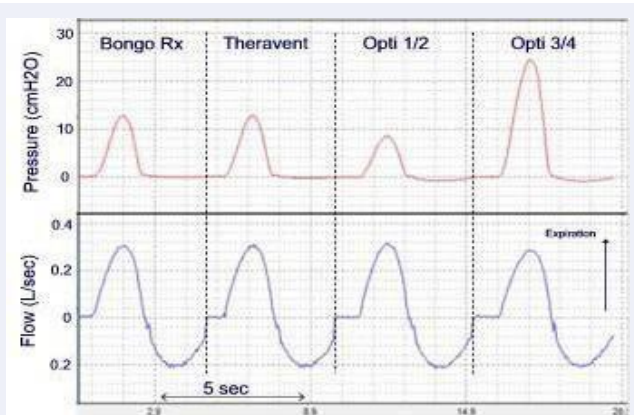
The results show that peak expiratory pressures with Theravent and Bongo Rx were identical and well within the range that the Optipillows EPAP Mask provided. Peak expiratory pressure with Theravent and Bongo Rx were between the peak pressures generated with Optipillows EPAP mask when the side vent was 50% and 75% closed. The results were equally similar at low and at high tidal volume. The peak pressure at large tidal volume was higher than with the pressure at smaller tidal volume, suggesting that expiratory pressure in humans would be proportional to the tidal volume. The resistance of the side vent on Optipillows EPAP Mask can be easily adjusted to approximately midway between 50 and 75% (approximately 60%) to obtain a resistance comparable to Theravent or Bongo Rx. Furthermore, Optipillows EPAP Mask with the side vent 75% closed provided expiratory resistance equal to another EPAP device, Provent Sleep Apnea Therapy; the calculated resistance at 100 ml/sec, the slope of the pressure-flow curve, and the peak expiratory pressure were comparable (unpublished data).

**Table 1:** Calculated resistance of the 3 EPAP devices at the flow of 100 ml/sec, 200 ml/sec, or from the slope of the pressure-flow curve between 100 to 200 ml/sec (i.e., Δ Pressure/ Δ Flow). Optipillows EPAP Mask was either ½ closed or ¾ closed. Values are mean ± SD.

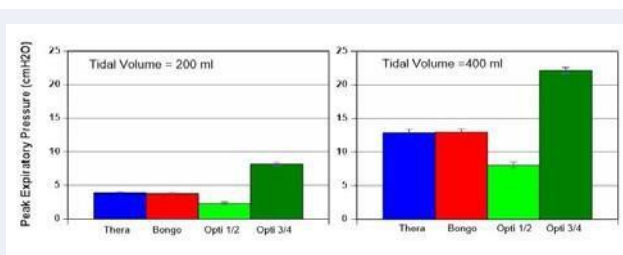
Flow Rate	Calculated Resistance of the Devices with steady unidirectional flow (cmH <sub>2</sub> O/L/sec)			
	Optipillows EPAP Mask 1/2	Optipillows EPAP Mask 3/4	Theravent	Bongo Rx
100 ml/sec	8.78 ± 0.91	28.51 ± 2.10	12.76 ± 1.05	13.21 ± 1.29
200 ml/sec	20.05 ± 1.40	54.90 ± 3.10	28.44 ± 1.23	28.89 ± 1.08
Slope	30.66 ± 2.06	76.56 ± 4.43	44.19 ± 1.32	45.36 ± 1.15



**Figure 3** The pressure-flow relationship for the three devices in a graphical format. The mean values shown in the table were used to plot the slopes. Opti 1/2 and 3/4 are Optipillows with the side vent 50% and 75% closed.



**Figure 4** Comparison of the pressure and flow during simulated breathing with 400 ml in the three EPAP devices. Opti 1/2 and Opti 3/4 are Optipillows with 50% and 75% resistance. With 200 ml, the peak flow and pressure, as expected, would be smaller (not shown).



**Figure 5** Peak pressure generated during expiration with simulated breathing using 200 ml and 400 ml volumes for the three EPAP devices. Thera =Theravent Snore Therapy, Bongo = Bongo Rx, Opti 1/2 and Opti 3/4 are Optipillows with the side vent 50% and 75% closed.

## DISCUSSION

The preferred treatment for obstructive sleep apnea is continuous positive airway pressure (CPAP). EPAP devices have become a viable option for the treatment of snoring and obstructive sleep apnea because of the abundance of data showing their safety and effectiveness [2, 3, 5, 16]. With EPAP, the pressure in the upper airway remains close to zero during inspiration and therefore upper airway collapse remains possible [12]. Nevertheless, the upper airway is thought to remain more dilated because of increased pressure during expiration, diminishing the potential for upper airway obstruction. To understand the effectiveness of EPAP devices, it is useful to know the EPAP device's resistance and the pressure they potentially generate during expiration. The measurements that we made are accurate and reflect the devices' performance. The measurement that we made using a steady flow at 100 ml/sec is typically reported about the EPAP devices' resistance. The simulated breathing measurements were done to assess how much pressure is generated during expiration in adult humans. The use of simulated breathing is useful because the breathing pattern can be controlled. There are some differences compared to breathing in humans. The flow wave with the respirator was a sinusoidal wave with a peak pressure or flow in the middle of expiration. During normal breathing, the pressure and flow

during expiration while using an EPAP device tend to exhibit a flattened plateau instead of a rise to a peak point [12]. Thus the peak pressure in human may be slightly less than predicted by simulated breathing. Otherwise, simulated breathing patterns represented normal breathing in tidal volume, frequency, and flow rate. The results show that Theravent and Bongo Rx have almost identical expiratory resistance and generate equal pressure during expiration. Yet, one EPAP device is cleared for the treatment of snoring (Theravent), while the other is indicated for the treatment of mild to moderate obstructive sleep apnea (Bongo Rx). The Optipillows EPAP Mask can provide resistance equivalent to Theravent or Bongo Rx when the side vent is closed midway between 50 and 75%. The Optipillows EPAP Mask has been cleared for snoring treatment but generates expiratory pressure equal to Bongo Rx. Bongo Rx is a prescription-only EPAP device, whereas Theravent and Optipillows are over-the-counter devices.

The Optipillows EPAP Mask with side vent 75% closed provided expiratory resistance and peak pressure comparable to a fourth EPAP device: Provent Sleep Apnea Therapy, which is indicated for all severities of obstructive sleep apnea (unpublished data). The side vent in the Optipillows EPAP mask is 12 mm long, and would be easy to estimate if it is approximately 50% or 75% closed, and somewhere in between. The patient can estimate 60% resistance on the Optipillows EPAP mask (approximately equal to Theravent and Bongo), and make adjustments thereafter based on their comfort. It is not necessary to be exact, because each patient generates pressure proportional to the size of their tidal volume, as shown in Figs 5. More importantly, the patient can select a resistance to get the most comfort and benefit.

We have taken much care to make sure we calibrate the pressure and flow before each experiment, and therefore, our measurements are accurate. The resistances of other devices are slightly different from the values that we calculated. For example, the resistance of Theravent calculated at 100 ml/sec was reported to be 30 cmH<sub>2</sub>O/L/sec [13]. Our measurements suggest that it is closer to 13 cmH<sub>2</sub>O/L/sec. It is possible that the reported values of resistance for other EPAP devices were obtained using different measuring tools to calibrate the pressure and flow and thus may account for some of the differences. Bongo Rx's resistance was reported in an abstract [14]. The values that were reported in the abstract were done at different flow rates, but are consistent with the values in the present study. For example at a flow of 166 ml/sec (10 L/min), they report a resistance value of 17.4 cmH<sub>2</sub>O/L/sec for Bongo, which is within the values reported in this study at 100 and 200 ml/sec (Table 1). The resistance is usually reported as the pressure generated at a flow of 100 ml/sec, but such value may be unreliable because the resistance at another flow rate would yield a different value, such as at 200 ml/sec. The slope of the pressure-flow curve is a much more reliable value to describe the device's resistance. We estimated the slope from the data in the abstract between 166 and 333 ml/sec, to be 50 cmH<sub>2</sub>O/L/sec, which is consistent with the values in Table 1. More importantly, in this study, we used one calibration method to test all three EPAP devices side by side. Thus the differences between the EPAP devices that we report in this study are accurate. We estimated that when the side vent is closed midway between 50 and 75% on Optipillows (approximately 60%), the resistance and expiratory

pressure were equal to Theravent or Bongo Rx. The Optipillows EPAP Mask has a resistance range of 2 to 75 cmH<sub>2</sub>O/L/sec and can be easily adjusted in small steps. It can be adjusted to 75% to make it equivalent to Provent. As importantly, a new user of EPAP devices may not be able to adapt to the high resistance of the EPAP device, but Optipillows EPAP Mask allows the patient to use minimal resistance while trying to adapt to the EPAP device.

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