Helpful Downloads

VCOM™ CPAP made easy

White Paper

SCAN ME

Sleep Review Article

SCAN ME

History and Future PAP Therapy:
Reevaluating the Role of IPAP in Therapy for OSA

William H. Noah, MD
Founder & Senior Medical Director
Sleep Centers of Middle Tennessee
Chairperson
Middle Tennessee State University Sleep Research Consortium
CEO
SleepRes

Current Volume:

1,000 Office Visits, Sleep Studies, and New PAP Setups per Week

SLEEP CENTERS℠ PLLC
of Middle Tennessee

January 2021:
90% increased CPAP usage during year 1
(312 vs 164 min, p-value< 0.00001, n=3884 patients)

JCSM | Journal of Clinical Sleep Medicine

SCIENTIFIC INVESTIGATIONS

Positive airway pressure therapy supplied by an integrated sleep practice associated with greater adherence among pre–Medicare-aged patients with sleep-disordered breathing

James M. Andry Jr, MD[1]; Gabriel Toban, MS[2]; Cynthia Chafin, Med[2]; William Noah, MD[3]

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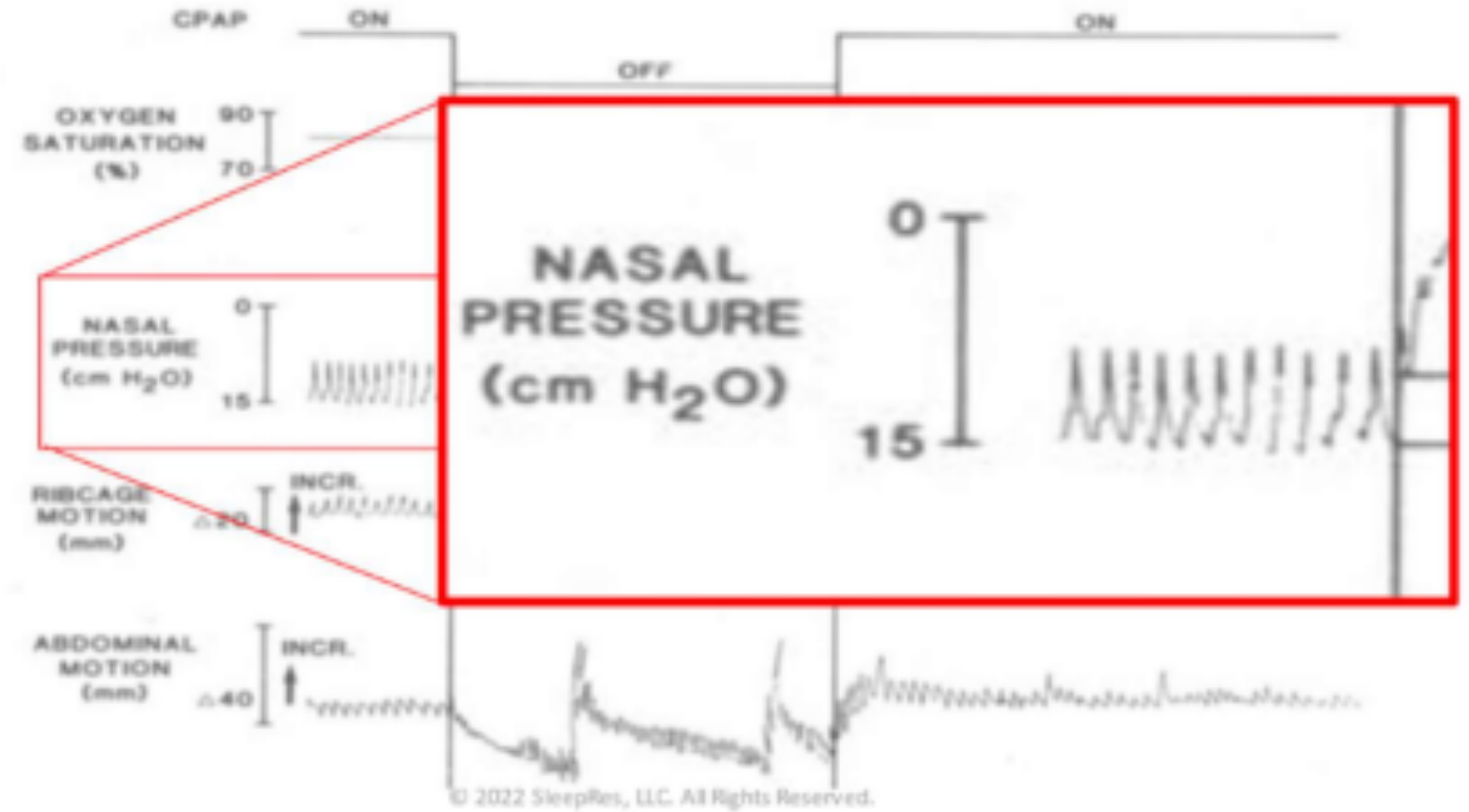
History Of PAP

- In 1878 Oertel used inspirations of compressed air to treat severe asthma
- In 1887 George Fell used a foot-operated bellows to ventilate opioid overdoses until they recovered
- Alvan Barach et al used PAP to treat pulmonary edema in 1930's
- Used frequently to treat ARDS in the 1970's
- Then in the 1980's to treat OSA

Sullivan et al, *Lancet* April 18, 1981: *"Reversal of Obstructive Apnoea by Continuous Positive Airway Pressure through the Nares"*

Early CPAPs Had Decreased Inspiratory and Increased Expiratory Pressures

1986, Kingman Strohl and Susan Redline



Sanders & Kern introduce Bilevel PAP in 1990

Obstructive Sleep Apnea Treated by Independently Adjusted Inspiratory and Expiratory Positive Airway Pressures via Nasal Mask*

Physiologic and Clinical Implications

Mark H. Sanders, M.D., F.C.C.P.;† and Nancy Kern, C.R.T.T., R.PSG.T.

Treatment of obstructive sleep apnea with nasal continuous positive airway pressure mandates simultaneous increases of both inspiratory and expiratory positive airway pressures to eliminate apneas as well as nonapneic oxyhemoglobin desaturation events. We hypothesized that the forces acting to collapse the upper airway during inspiration and expiration are of different magnitudes and that obstructive sleep-disordered breathing events (including apneas, hypopneas and nonapneic desaturation events) could be eliminated at lower levels of EPAP than IPAP. To test these hypotheses, a device was built that allows the independent adjustment of EPAP and IPAP (nasal BiPAP). Our data support the hypotheses that expiratory phase events are important in the pathogenesis of OSA and that there are differences in the magnitudes of the forces destabilizing the upper airway during inspiration and expiration. Finally, applying these concepts, we have shown that by using a device that permits independent adjustment of EPAP and IPAP, obstructive sleep-disordered breathing can be eliminated at lower levels of expiratory airway pressure compared with conventional nasal CPAP therapy. This may reduce the adverse effects associated with nasal CPAP therapy and improve long-term therapeutic compliance.

(Chest 1990; 98:317-24)

OSA = obstructive sleep apnea; CPAP = continuous positive airway pressure; IPAP = inspiratory positive airway pressure; EPAP = expiratory positive airway pressure; PSG = polysomnography; AI = apnea index; DEF = desaturation event frequency; OA = occlusive apnea; CA = central apnea; MA = mixed apnea; OH = obstructive hypopnea; CH = central hypopnea; HI = hypopnea index

Results of Sanders and Kern (1990)

Belief that EPAP treats Apneas and IPAP treats hypopneas
"Crack the airway open with EPAP then blow it open with IPAP"

Belief that inspiratory events (hypopneas/snoring) require higher inspiratory pressure

Thus increase IPAP for hypopneas during titration and their initial bilevel titration protocol is still the basis of the AASM titration guidelines (2008) recommended today

From 1995, bilevel PAP has not shown improved adherence in uncomplicated OSA

Despite little clinical evidence for uncomplicated patients, bilevel PAP has generated financial benefits for suppliers and manufacturers

Philips Introduces CFLEX in 2003

A UNITED PUBLICATION

WWW.HMENEWS.COM
VOLUME 9, NUMBER 1
JANUARY 2003
$7.00

HME News

THE BUSINESS NEWSPAPER FOR HOME MEDICAL EQUIPMENT PROVIDERS

NEWS

- NCB: Industry plays waiting game. *See Page 4*
- CMS issues revised IR rule. *See Page 4*
- Industry fears CMN change. *See Page 6*
- Healthcare spending skyrockets. *See Page 6*

PROFILE

Don Clayback brings experience in accounting, HME and consulting to his new post as head of The MED Group's National Rehab Network. Clayback, who replaces W.B. Mick, will oversee MED's National Respiratory Network as well. ➤ *See Page 13*

SMART TALK

- Payment discount factor. *See Page 14*
- A patient's right to choose. *See Page 14*
- GOP: What to expect. *See Page 15*
- CMNs and audits. *See Page 15*

DEPARTMENTS

HME Providers *Page 17*

- AHP rolls out e-CMN initiative big time.
- O2 Science breaks new ground in Northwest.

Rehab *Page 21*

- Are providers skirting the law in Georgia?

Respironics flexes CPAP

'Breakthrough' technology makes exhaling easier

BY JIM SULLIVAN

MURRYSVILLE, Pa. — A new CPAP technology that provides pressure relief during exhalation is being touted by some as the most significant basic "box" breakthrough in years, if not ever.

Developed by Respironics and now equipped on every REMStar Pro CPAP machine, the new C-Flex technology tracks a patient's breathing and, during exhalation, lowers the amount of pressure delivered. The ramp-down is not as precipitous as a bi-level drop, but the perception of relief, even from a layman's appreciation, is substantial.

C-FLEX TRACKS *and reacts to a patient's expiratory flow to deliver the appropriate amount of pressure on a breath-by-breath basis.*

"C-flex has made CPAP obsolete," said John

Continued on PAGE 33

ACQUISITION

Investment firm rolls dice again on HME

BY MIKE MORAN

KNOXVILLE, Tenn. — Allied Capital Corp launched its second foray into the HME market last month, and if this deal turns out as well as the company's first HME venture, stockholders in the $2.3 billion investment company will be jumping for joy.

Allied first entered

Continued on PAGE 36

FACTORING: 'Margin for error is small'

Expiratory Pressure Reduction Algorithms

1) Little evidence of increased adherence particularly in larger RCTs
(Bakker et al 2010, Pepin et al 2009)

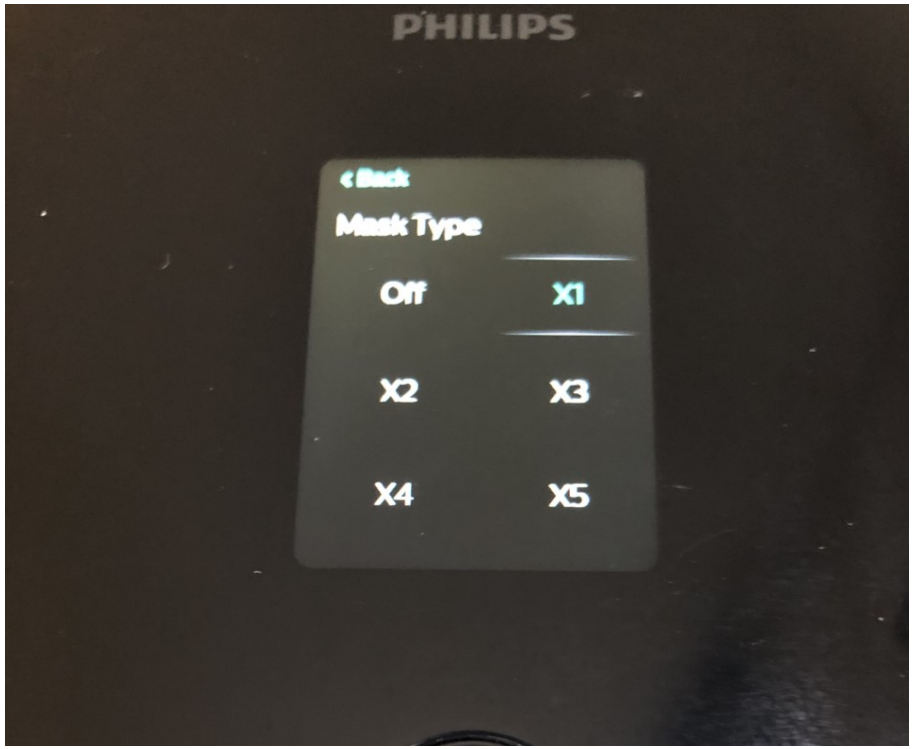
2) Associated with compromised therapy
(Zhu et al 2016)

3) Pressure reductions do not transmit to pharynx, merely to the mask
(Masdeu et al 2012)

Engineers engineer to the face, not the pharynx

Mask Compensation Algorithms (Initially introduced Philips in 2009)

React Health, formerly 3B Medical
Luna G3



Philips Respironics Dreamstation 2

Mask Compensation and Resistance

Large → Medium → Small →Extra-Small

Increasing Resistance →

Mask Resistance Compensation Algorithms

Further increasing IPAP to offset increased resistance in certain masks (ie nasal pillows) increases velocity (jetting) against nasal mucosa

Higher IPAP may lead to increased adverse effects such as aerophagia, leak, mouth opening, and potentially TECSA

Remove the advantage of high resistance interface in decreasing IPAP and increasing EPAP which may reduce the overall device pressure setting

Bottom Line Regarding Mask Type Settings on PAP Devices

Respironics (Philips):

1) never studied effects of mask compensation algorithms on PAP acceptance or therapy

2) never even tested mask resistance compensation algorithms on volunteers/patients (they thought it was just “engineering”)

Testing would have found:

1) 100% of new patients preferred the FFM setting with a nasal pillow interface
2) no effect on therapy

It was just the “belief” that maintaining IPAP was priority in therapy

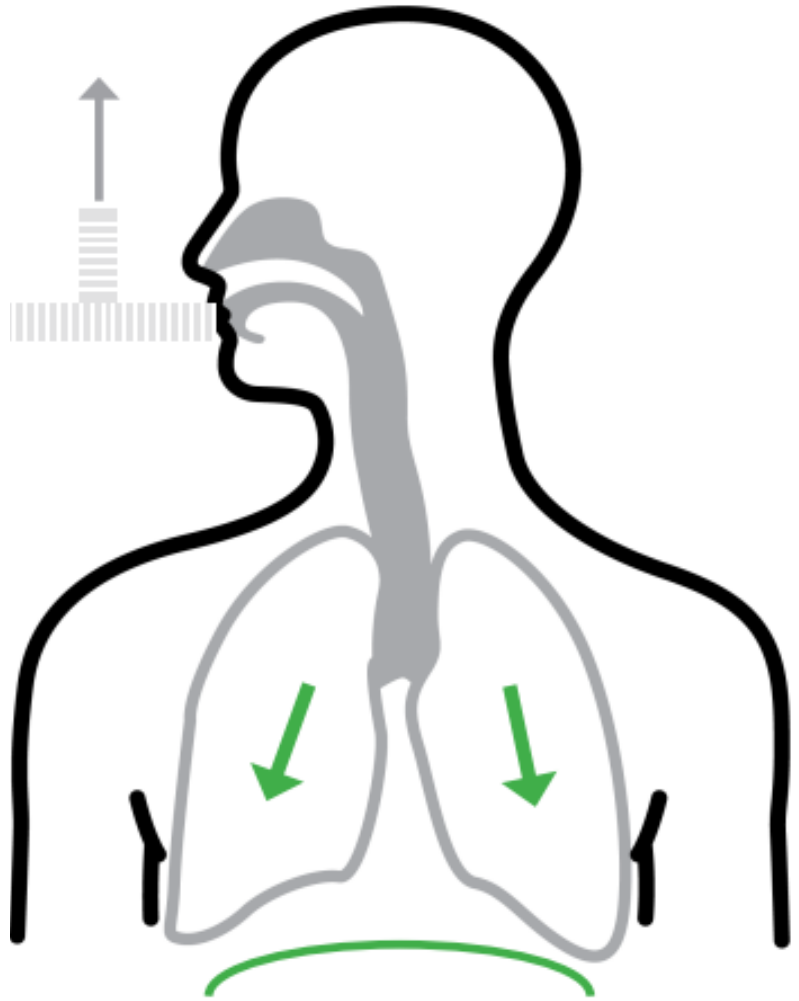
The 3 Major Actions of EPAP on the Pharyngeal Airway:

The First Two apply to all OSA patients

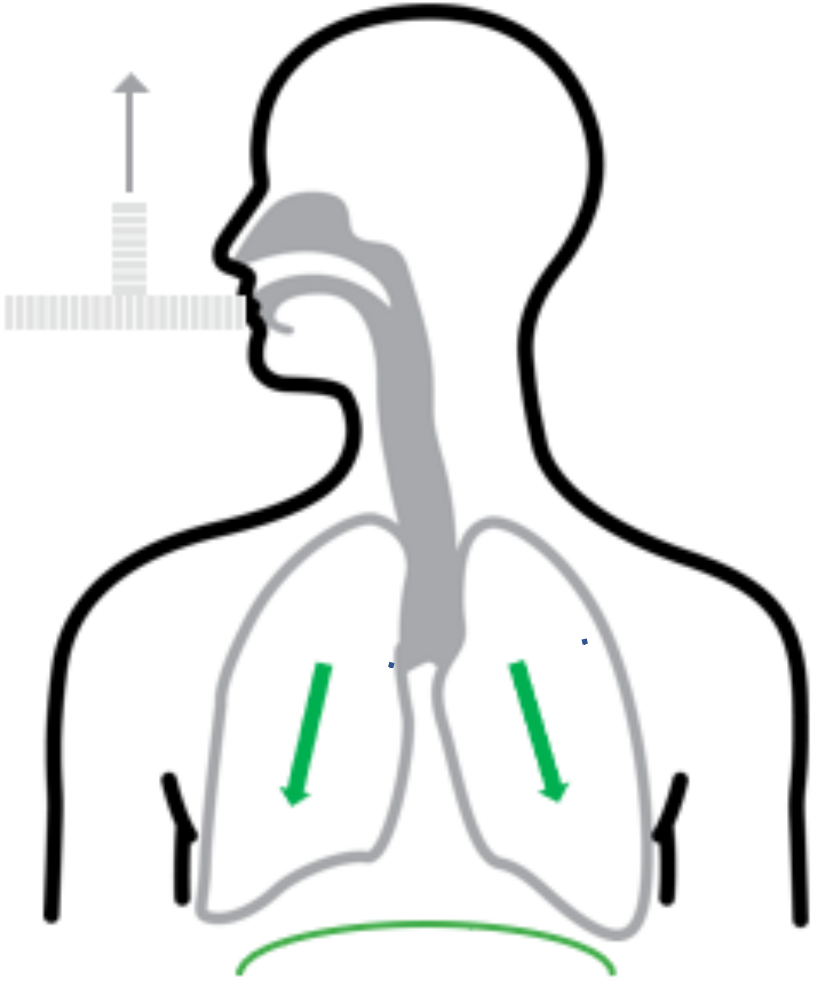
EPAP (particularly EEP):

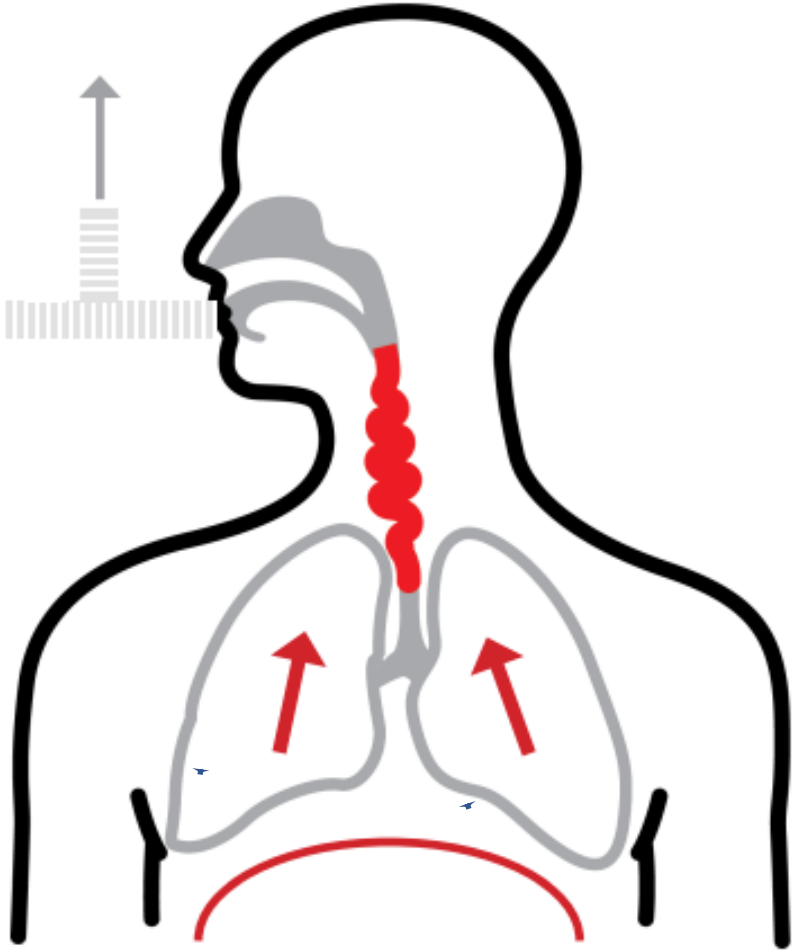
- 1) **Increases** Cross-Sectional Airway
  Reduces inspiratory resistance (effort)
  (Darcy-Wiesback equation)
- 2) **Increases** End Expiratory Lung Volume (EELV)
  Stabilizes UA (tracheal traction)

- **IPAP does not increase EELV**



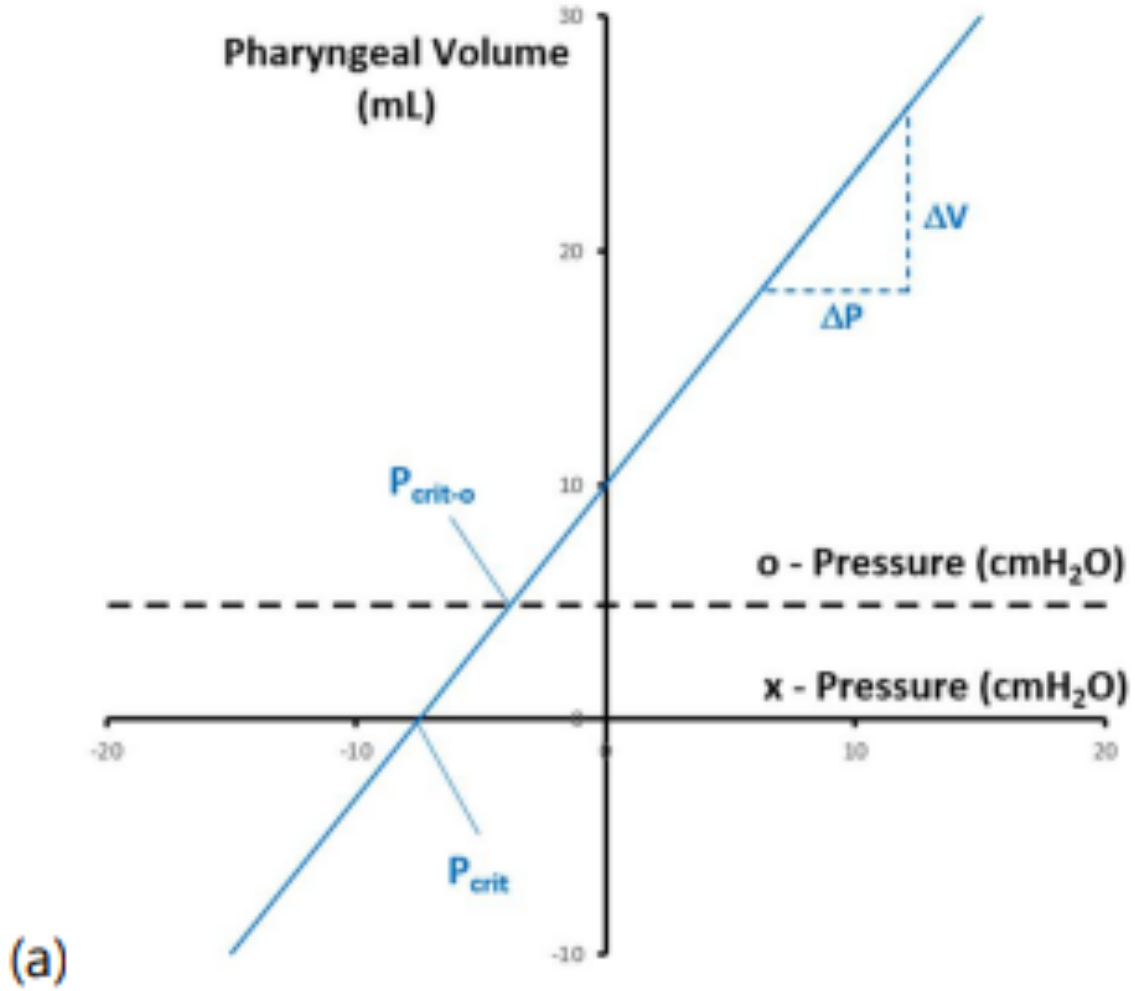
Optimal EPAP vs. Reduced EPAP





End Expiratory Pressure in Relation to P_{Crit}

P_{crit} is a Critical Time, not just a Pressure



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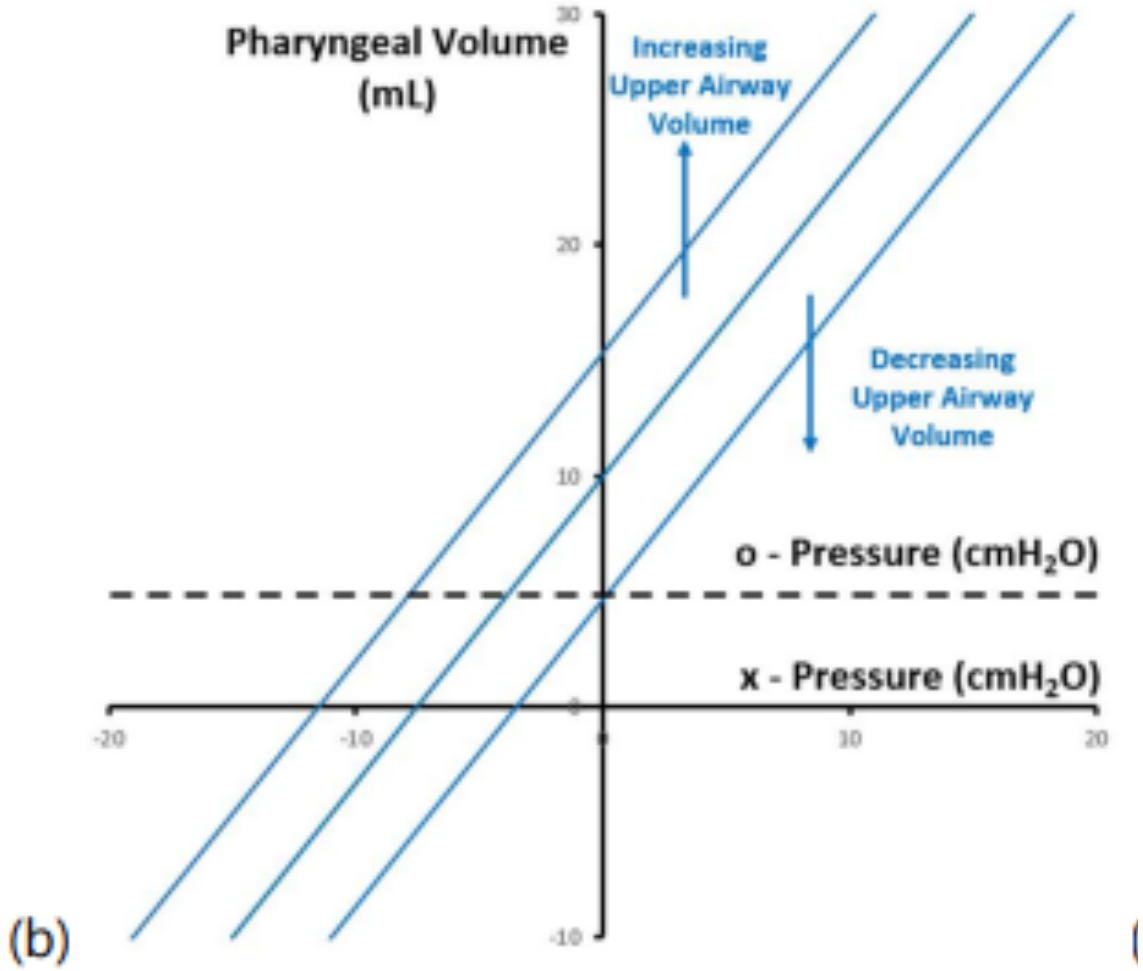

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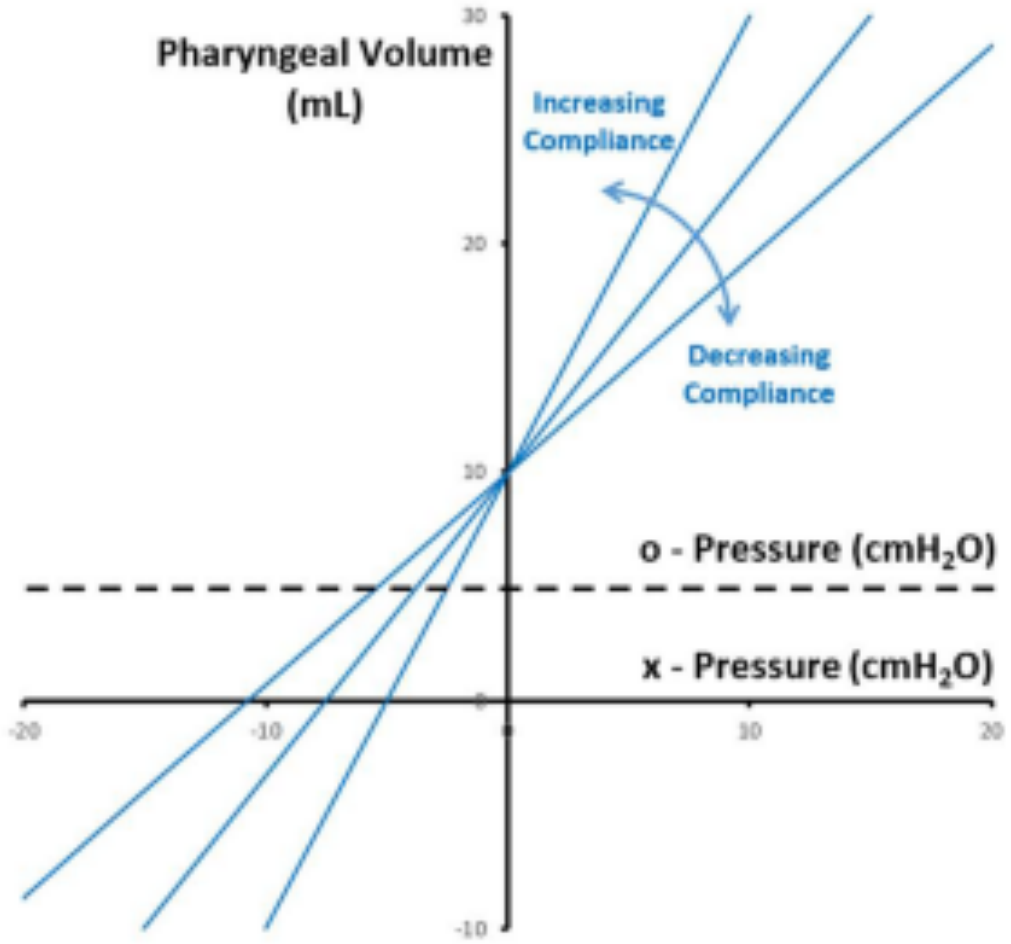
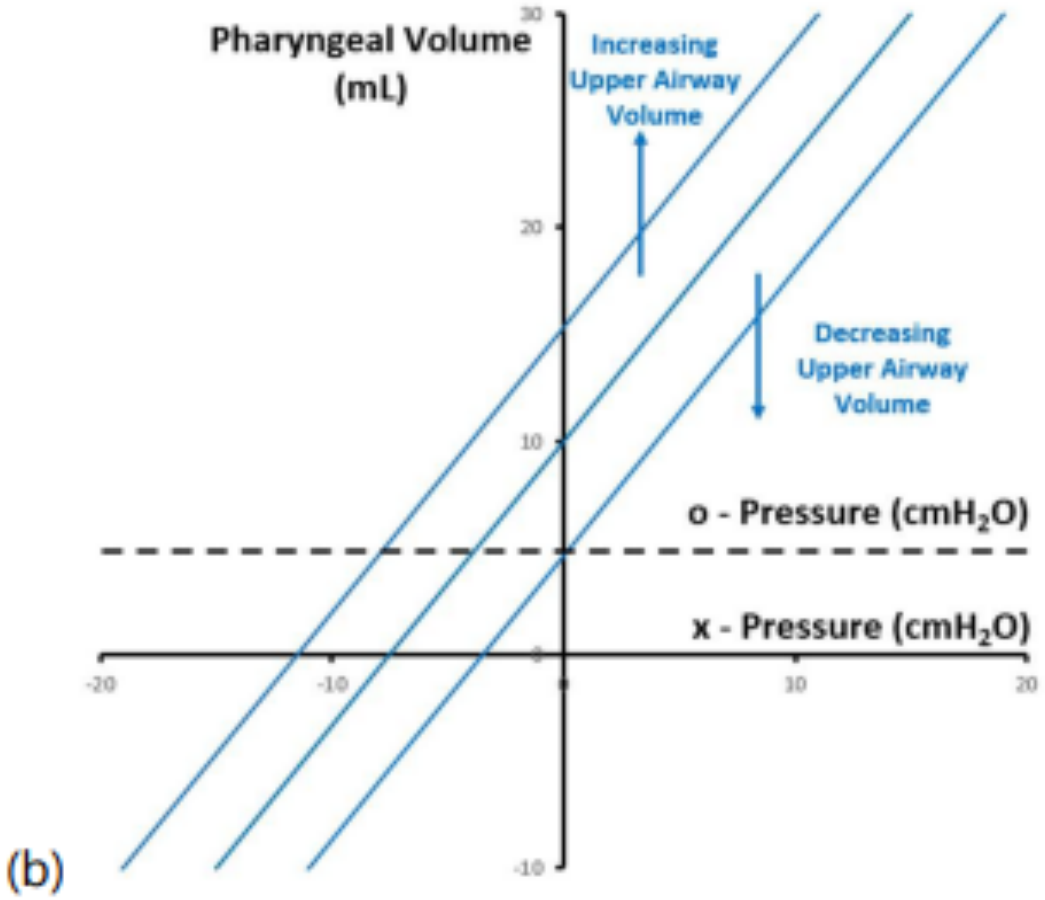
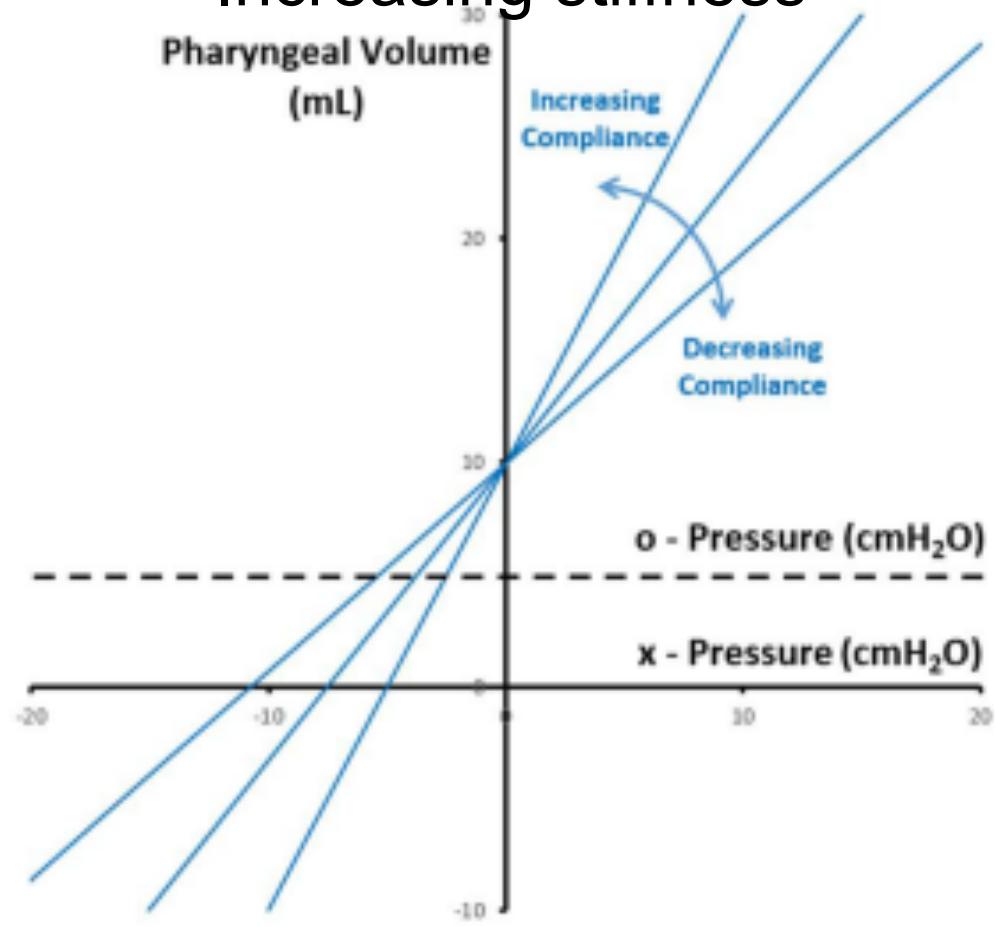


EPAP prevents obstruction or collapse of the pharynx by...

Increasing volume



Increasing stiffness



End-Expiratory Lung Volume Matters:
Why OA, HGN, UPPP, etc are Inferior Therapy

- Heinzer et al found manipulating lung volumes with an iron lung could:
  - (2006) Reduce the mean AHI in half (>60 to <30) by merely increasing EELV (no PAP)
  - (2005) Change therapeutic PAP level required between 5 cmH2O and 17 cmH2O

- Stadler et al (2010) compressed the abdomen with a pneumatic cuff to decrease EELV, and found that the pharynx was easier to collapse in obese males with OSA

The Third Advantage of EPAP (EEP): Decreased Work of Breathing (WOB) in Obese Patients

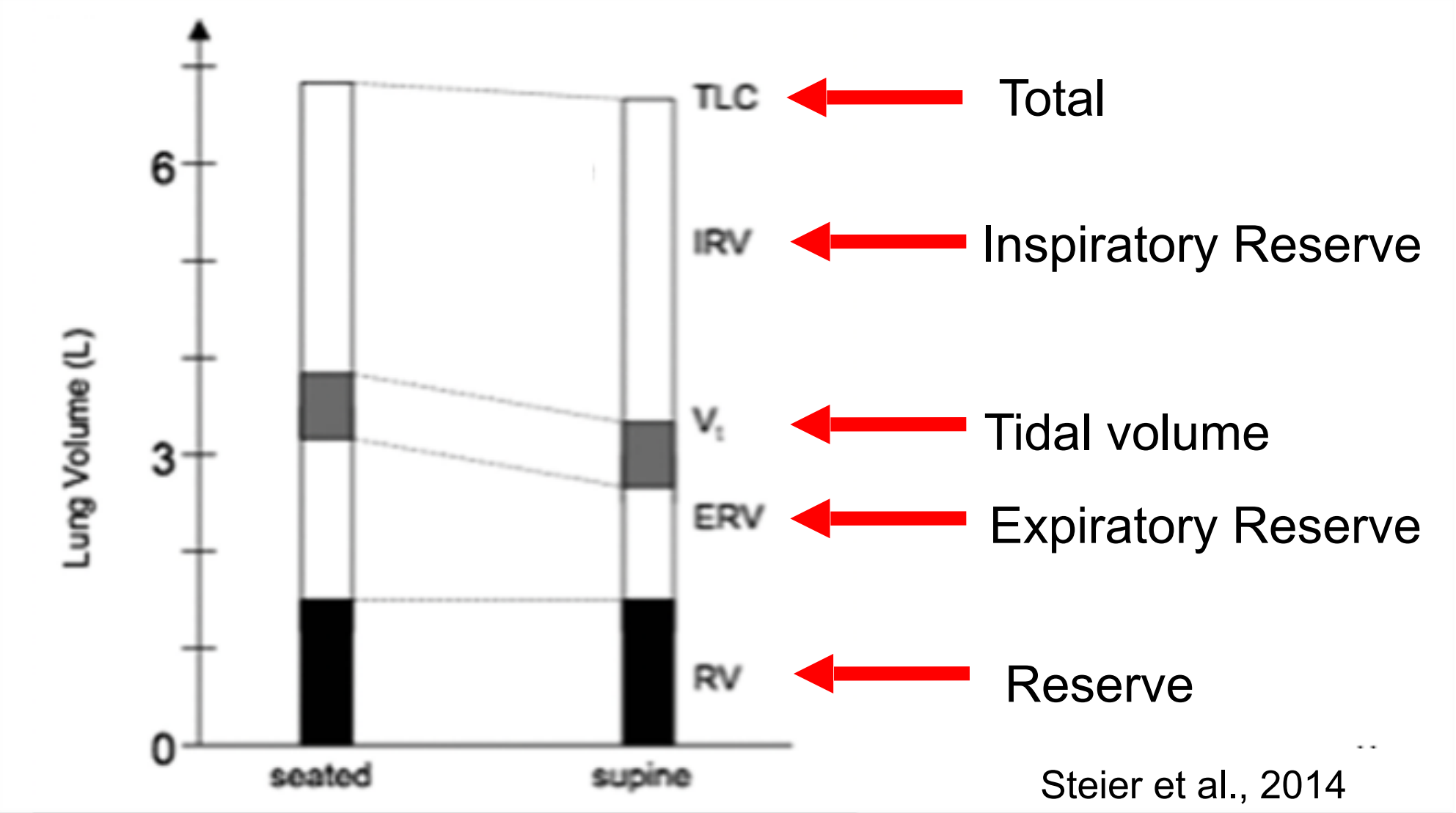
End-expiratory pressure (EEP)…

… increases EELV (FRC)

…which increases lung/chest wall compliance

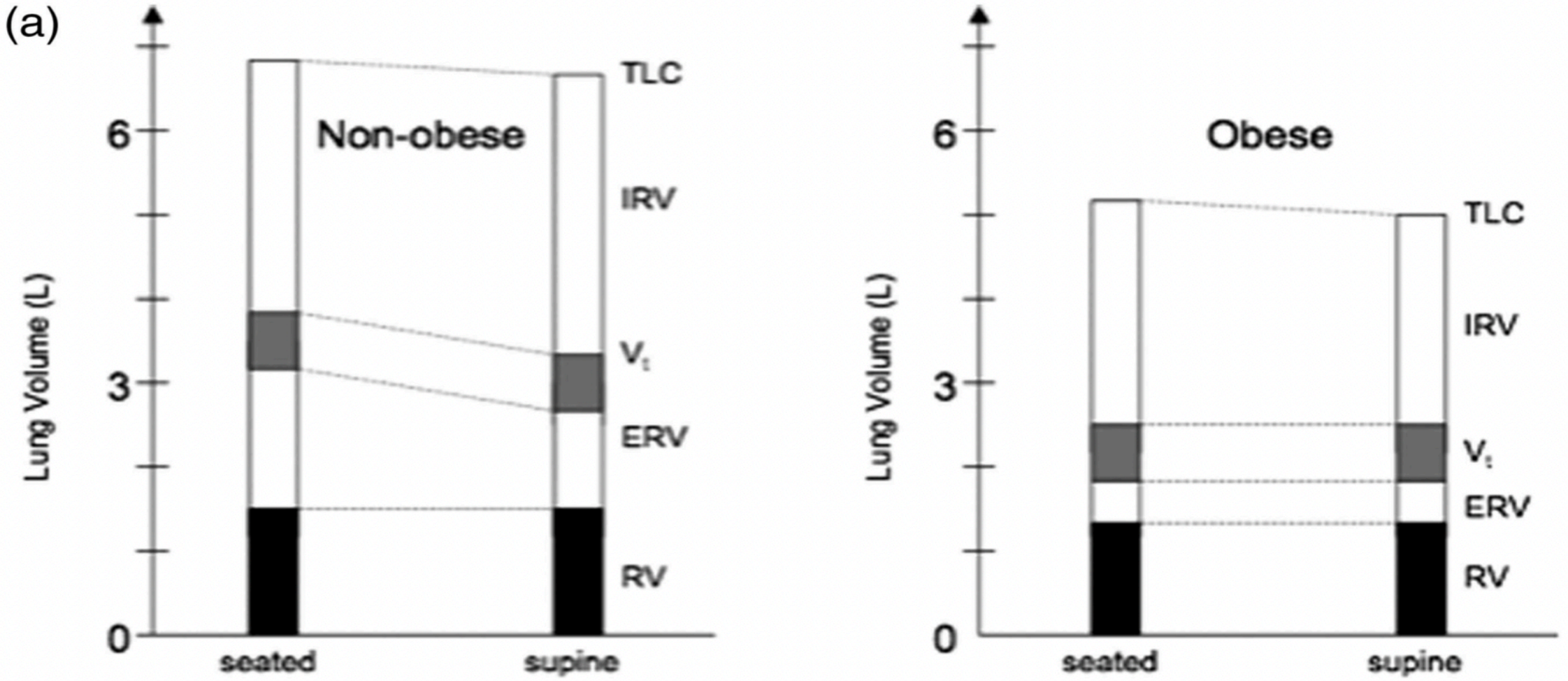
…and decreases the increased elastic work of breathing in obese individuals

Components of Lung Volume

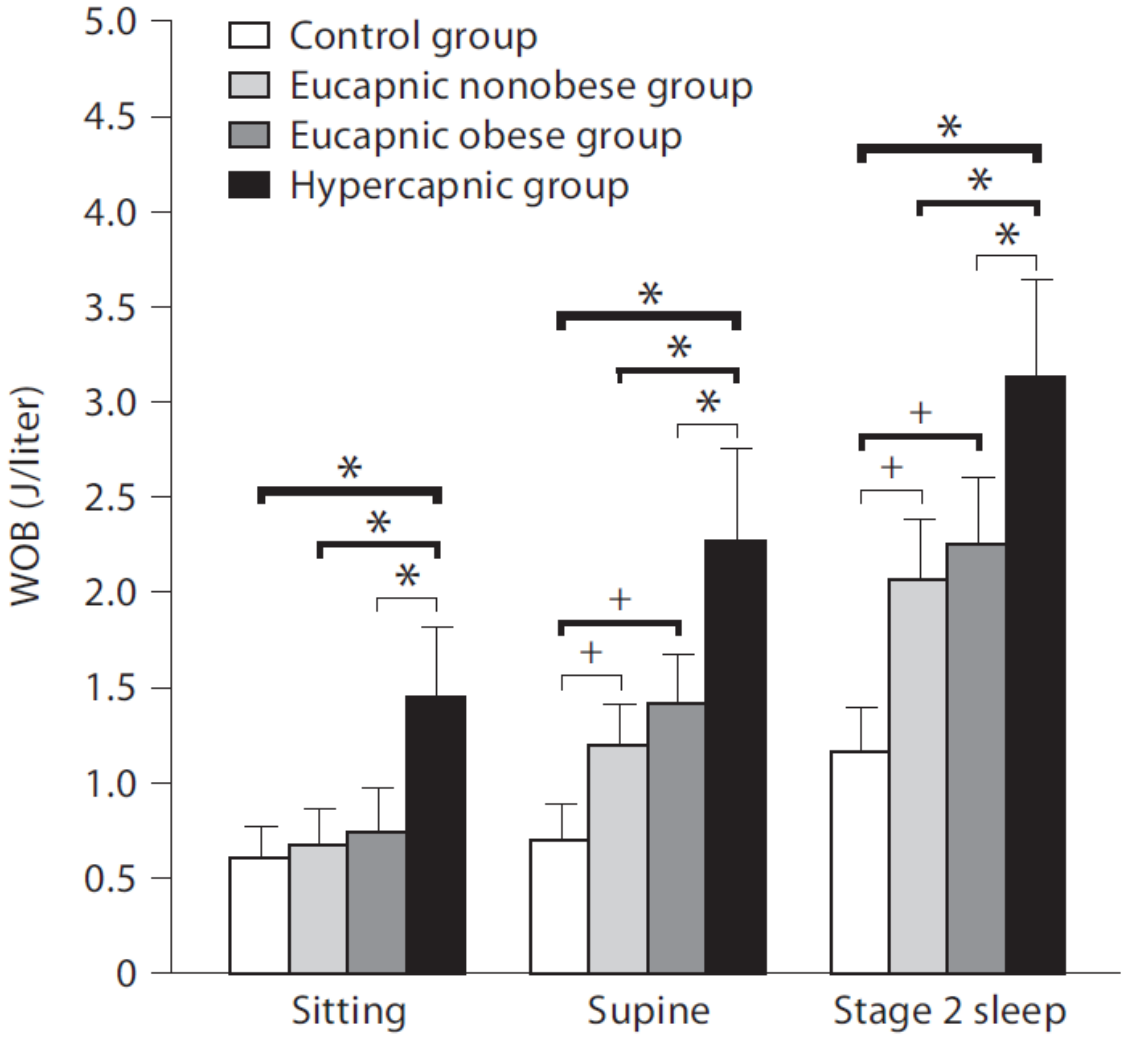


Steier et al., 2014

Obesity and Lung Volume
(Steier et al 2014)



Progression of Work of Breathing in OSA
(Lee et al 2016)



Metabolic Compensation

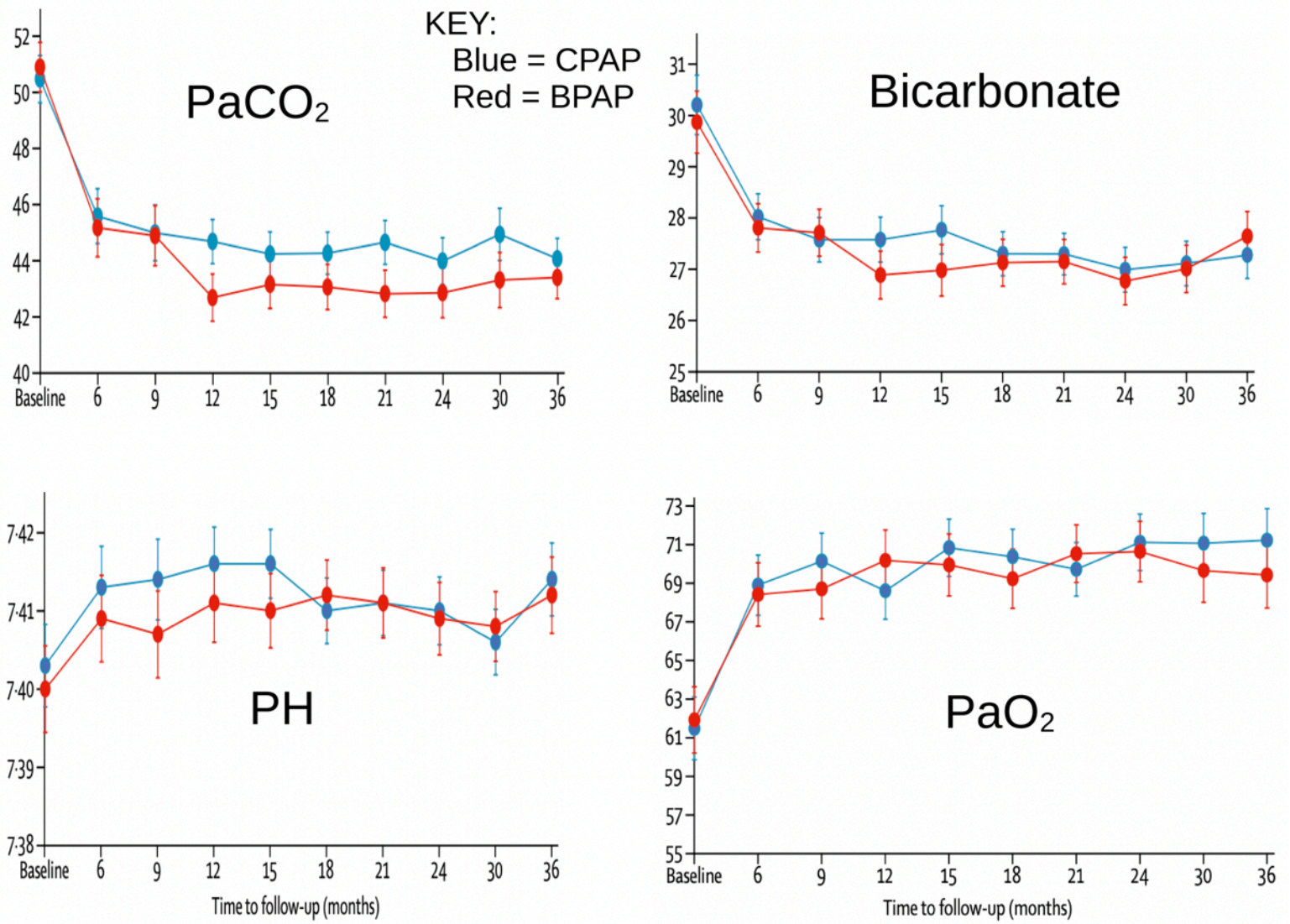
Why do patients develop chronic hypercapnia (elevated CO2)?

What determines when someone develops chronic (not acute) respiratory failure?

$$P_{AlveolarO2} = P_{InspO2} - P_{CO2} / R$$

CPAP equal to NIV in OHS

(Masa et al., 2019)



- Masa et al. compared CPAP to NIV in OHS
- All parameters improved significantly with both CPAP and NIV including hospitalizations

Since 1990, many PAP Advances have Focused on IPAP > EPAP or maintaining IPAP

Both Sanders and Kern (1990) and Resta et al found that in the setting of adequate EPAP that IPAP (at levels > EPAP) had some effectiveness with hypopneas

But they did not find (nor has anyone else) that IPAP is superior to EPAP in resolving hypopneas

The widespread dogma of “crack the airway open with EPAP and then blow it open with IPAP” has little evidence to support it

Reducing EPAP below optimal level destabilizes the upper airway (and in that setting higher IPAP can reduce obstructive events)

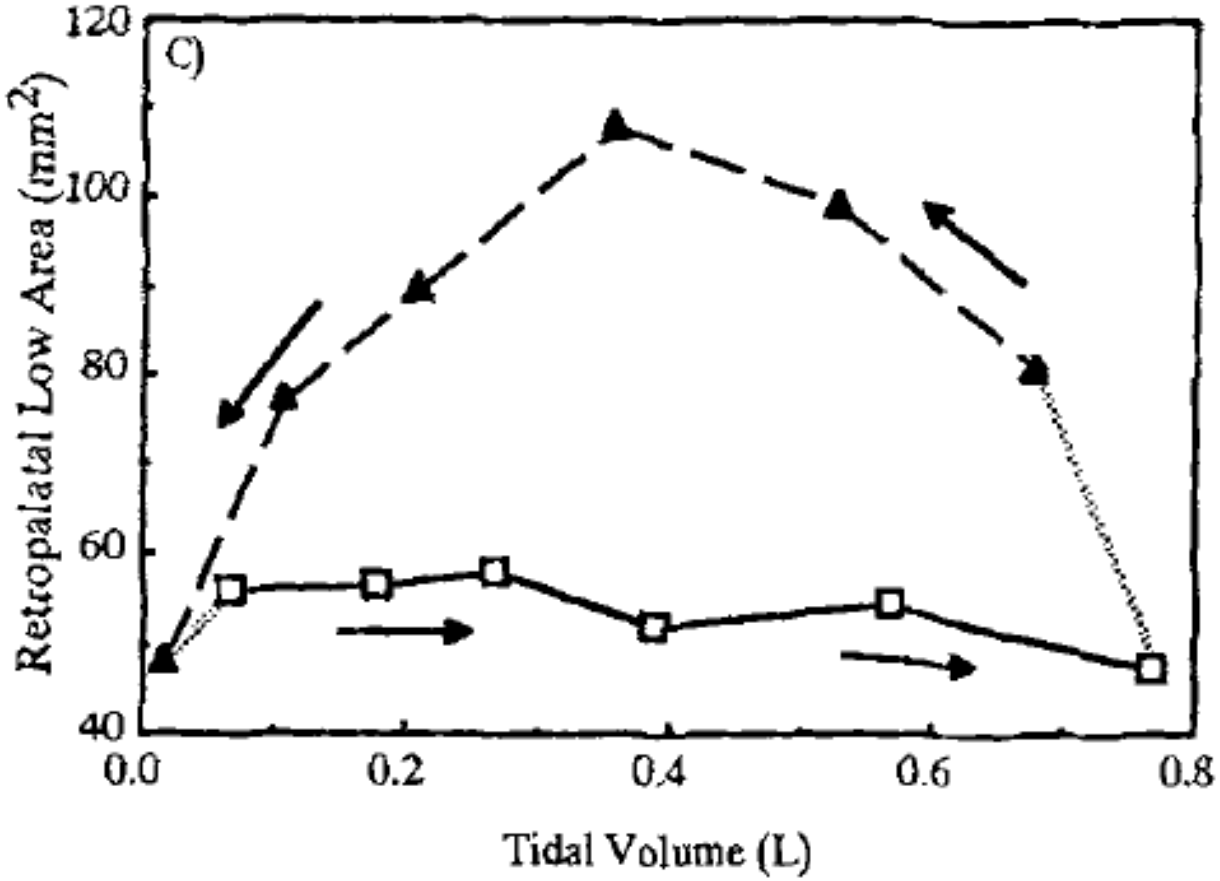
The concept that IPAP is best to treat hypopneas and EPAP is best to treat apneas is simply not true.

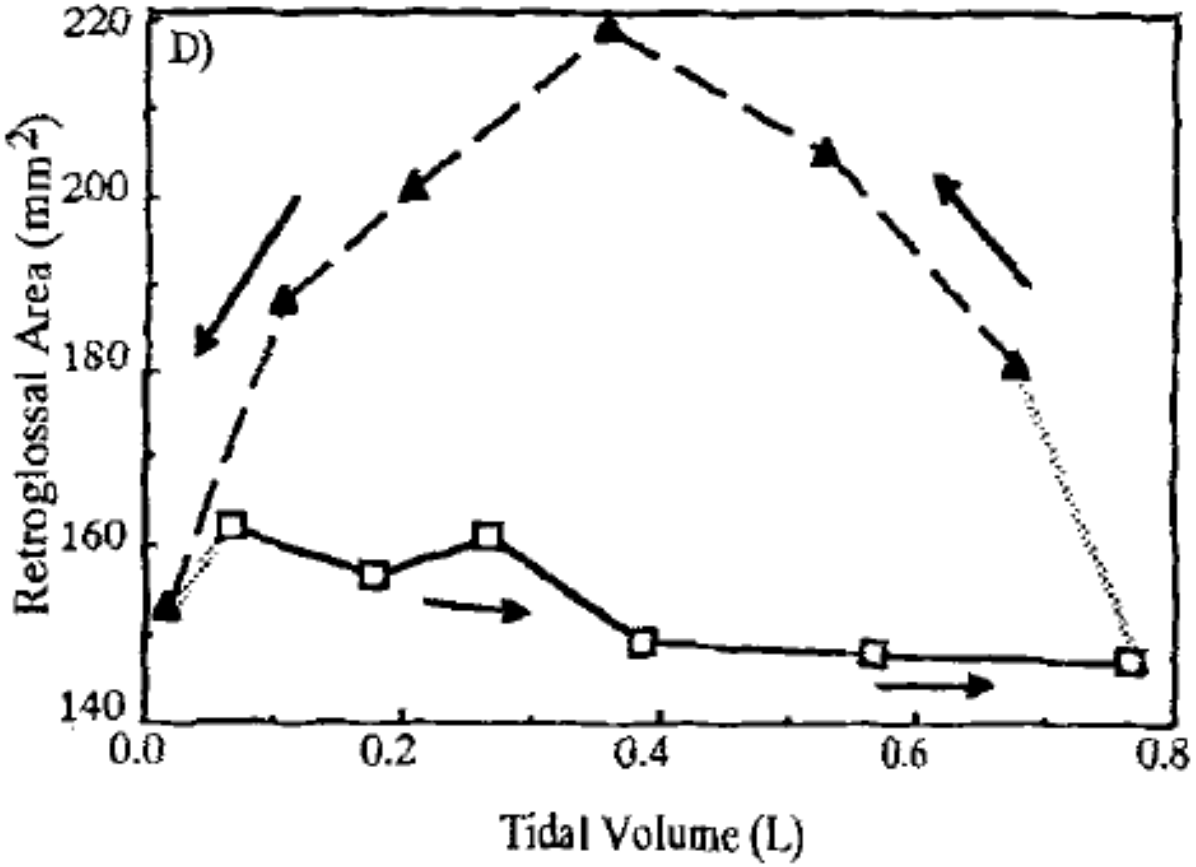
Adverse Effects of IPAP>EPAP

- Increased Inspiratory Resistance and Effort
- Aerophagia
- Unintentional Leak/Mouth Openings
- TECSA

Inspiration Obstruction?

Lung volume greatly expands further stabilizing the airway





Schwab et al 1993

Pharyngeal Viscoelastic Nature Overlooked: Starling Resistor Model is Misleading

Changes in airway diameter (shape or folds) have a time constant to change:

- not represented by balloon (Starling model)
- Likely unique for each airway

End-Expiratory airway shape extends into Inspiration (and vice versa)

Examples:
1) Nasal EPAP devices
2) HGN stimulators

Lung elasticity recoil pressure is increased in patients with OSA

Abdeyrim et al., 2015, found increased lung elastic recoil pressure in patients with OSA

May explain the increased UA resistance beginning during expiration (Sanders 1983)

Think EPAP and less IPAP

Apneas and hypopneas occur at critical pressures and time are determined by:

- The volume of the pharynx
- The volume of the lungs
- The stiffness of the pharyngeal walls

And the viscoelastic nature and elastic recoil

All of these are determined by EPAP, ***NOT*** IPAP

Does IPAP Increase Pharyngeal Crossectional Area or Just Increase Inspiratory Pressure Gradient ?

Reducing IPAP relative to EPAP Needed to be investigated

- After 30 years of IPAP > EPAP, adherence rates remain poor

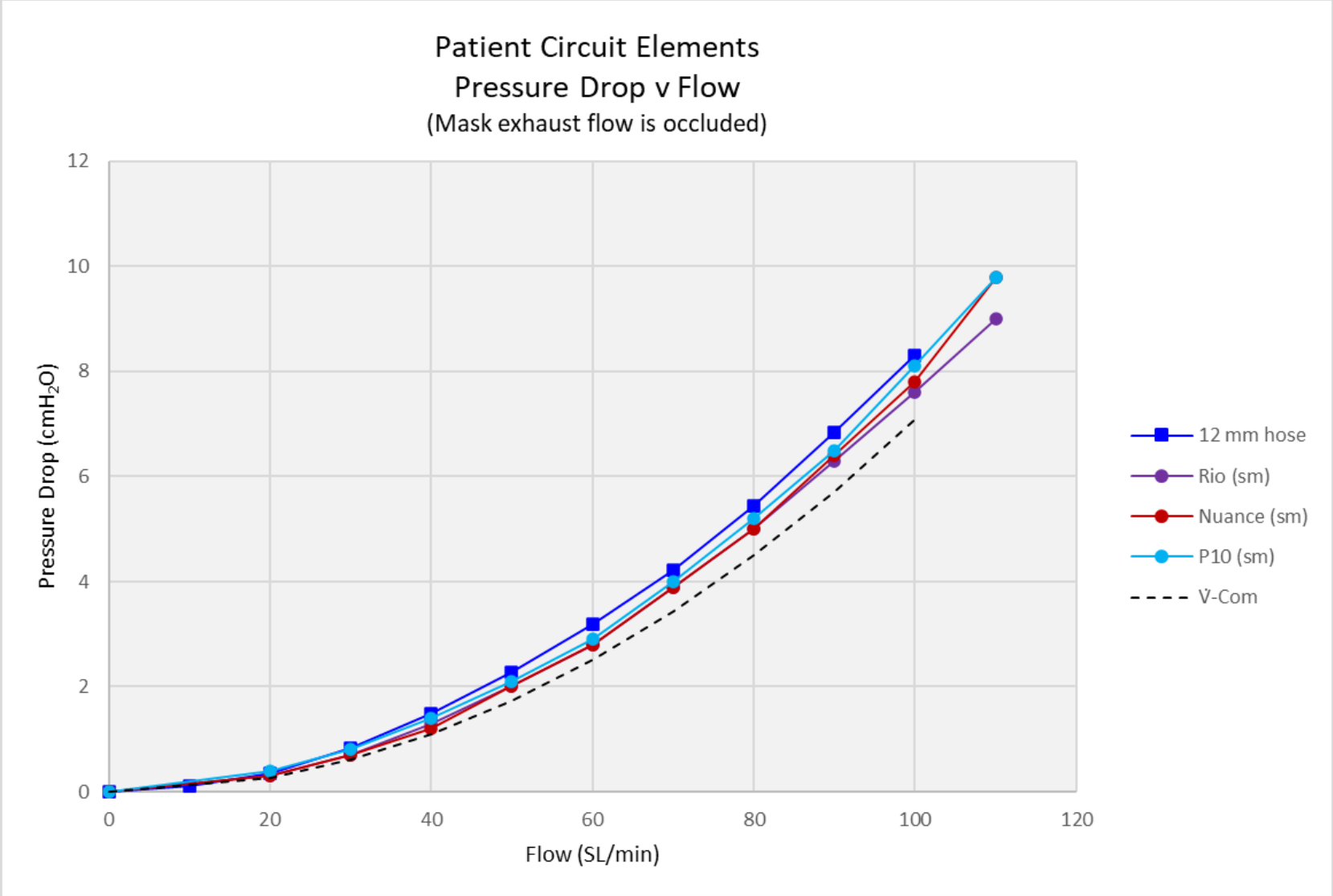
- There is an optimal EPAP to stabilize each airway

Yet, no commercially available bilevel device can reduce IPAP < EPAP so……..

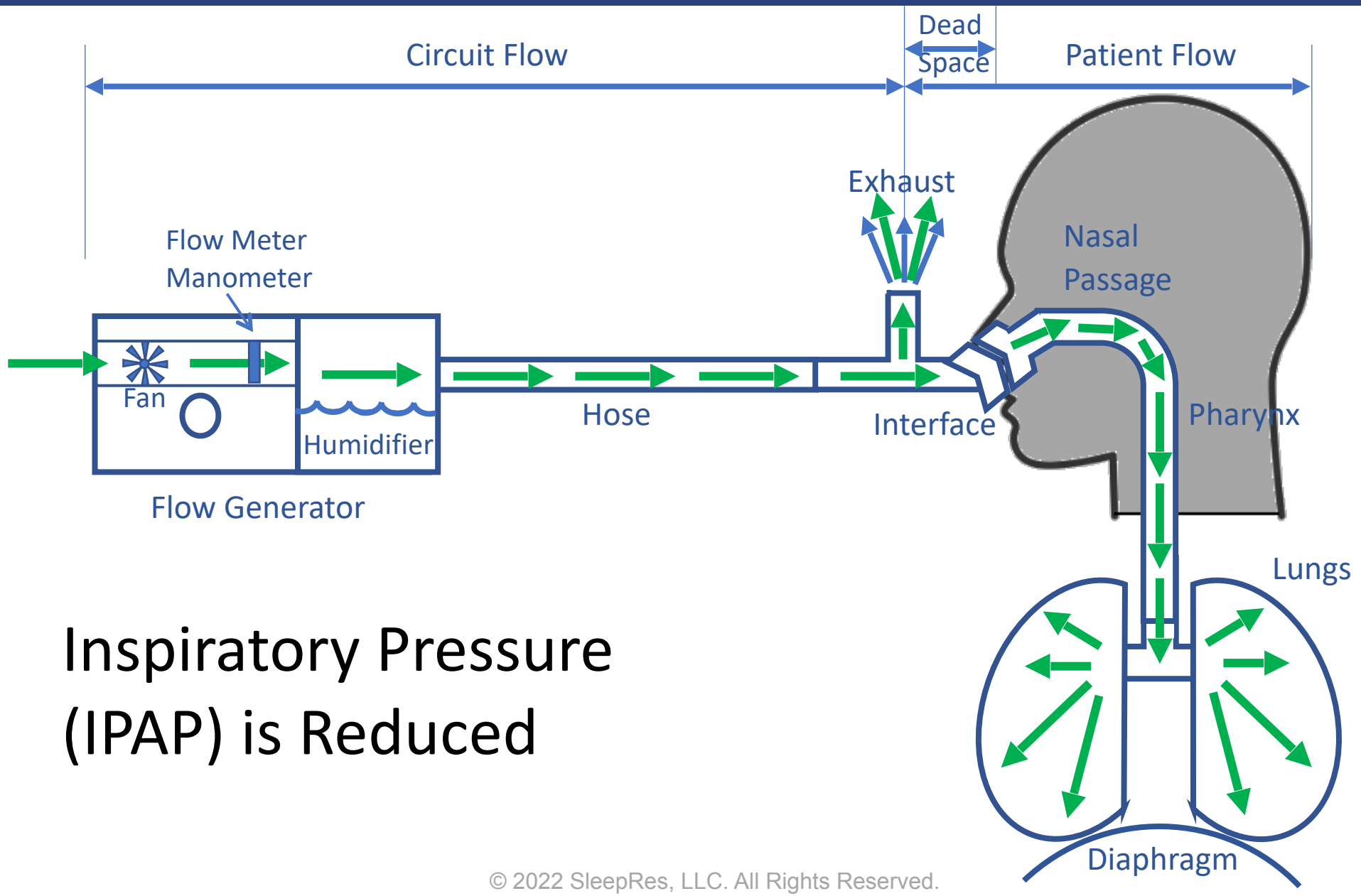
V̇-Com™ : Testing the Theory

- Adding non-compensated resistance
- **July 2021**: Design and 3-D Print an inline resistor
  - Resistance to flow: 2.0 cmH2O at 50 L/min
  - Dropped IPAP, but maintained EPAP
  - Comfort was obvious
- **January 2022**: Redesign resistor for injection molding
  - Resistance to flow lowered: 1.7 cmH2O at 50 L/min
- **June 2022**: V̇-Com™ introduced at APSS
  - Now with FDA requirements met, patient use began

Resistance in the PAP Circuit

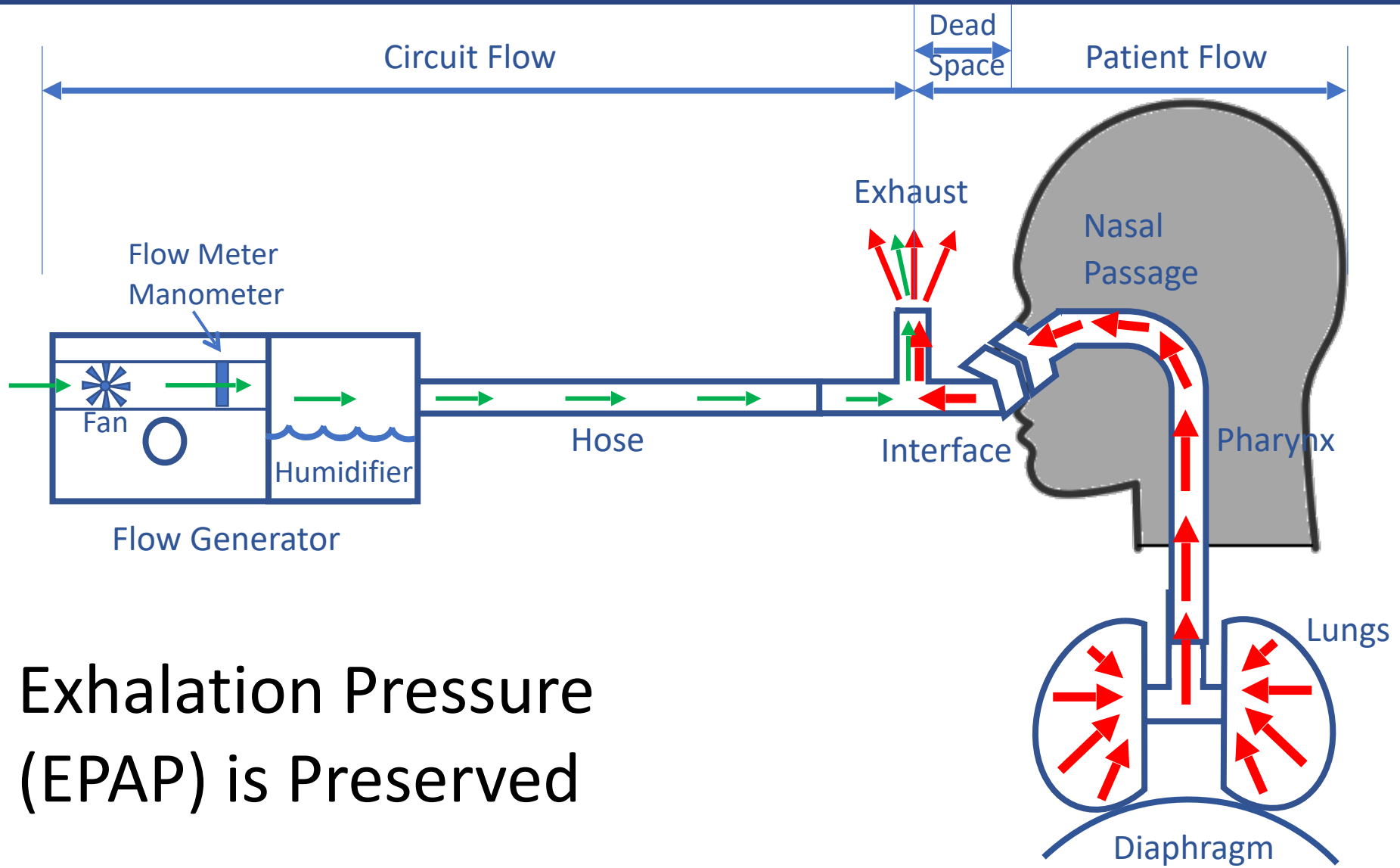


Inspiration: High Flow Large Pressure Drop



Inspiratory Pressure (IPAP) is Reduced

Exhalation: Low Flow Minimal Pressure Drop

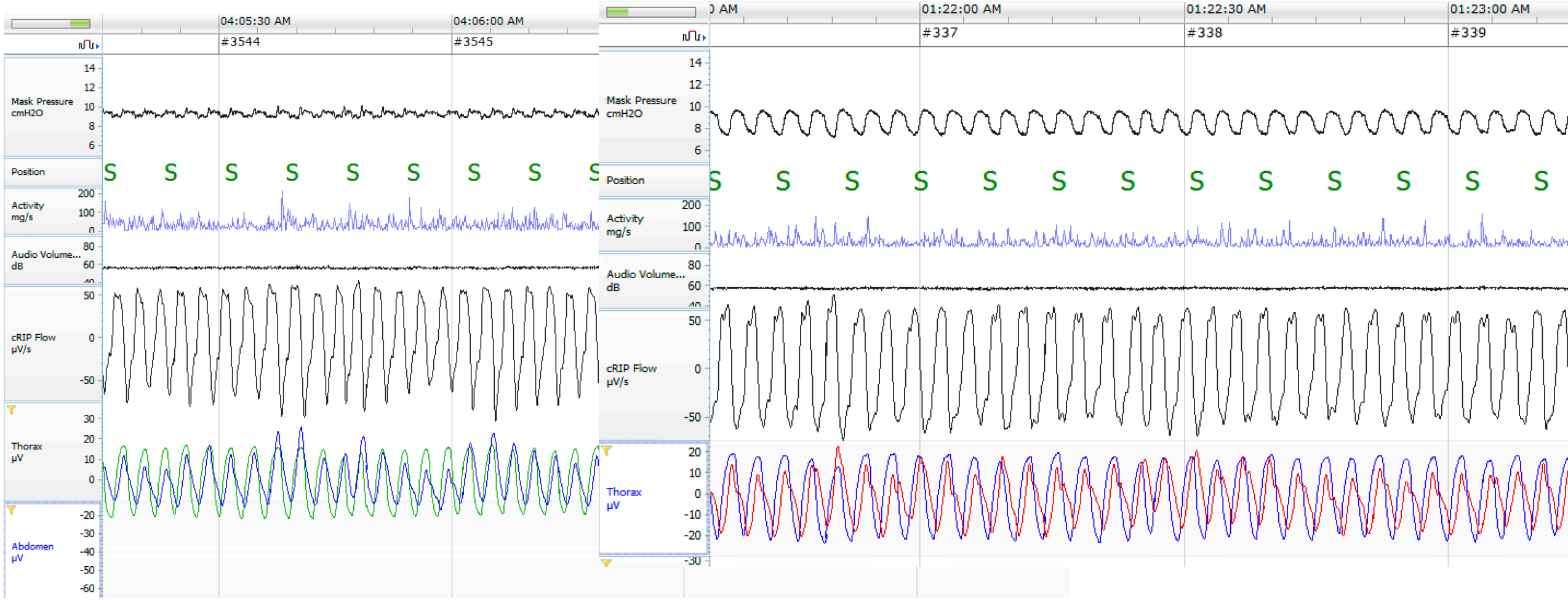


Exhalation Pressure (EPAP) is Preserved

V̇-Com™: Does it Effect Therapy?

Parameter	Participants	No V̇-Com	Std. dev	V̇-Com	Std. dev	Outcome w/ V̇-Com**	% Improved by V̇-Com™
P95%/ 90% Pressure (cmH_2O)	n=61	11.23	2.82	11.33	3.01	No difference	N/A-
AHI (events/ hour)	n=61	2.15	2.37	1.79	1.75	Improved (p-value<0.04)	69% (n=42/61)
Leak (L/min)	n= 43*	12.06	9.50	8.00	7.27	Improved (p-value<0.0001)	88% (n=38/43)
Usage (hours)	n=61	7.27	1.33	7.54	1.43	Improved (p-value<0.03)	64% (n=39/61)

2022 Data from University of Utah



V̇-Com™ Comfort Data in Patients Initiating PAP

A large DME company in the midwestern US conducted a trial of 47 patients who experienced CPAP during their set-up at their prescription pressure using the same interface both without and then with the V̇-Com™ in the circuit. Patients were then asked 3 questions regarding their experience.

98% (n=46/47) felt CPAP was *more comfortable* with the V̇-Com™

98% (n=46/47) believed they were *more likely to use CPAP* with the V̇-Com™

83% (n=39/47) were *willing to pay* $35 extra out of pocket to have V̇-Com™ in their CPAP circuit

(Their manuscript is currently being submitted)

Long-Term CPAP Patients Choose V̇-Com™

77% of long-term CPAP users prefer PAP *with* V̇-Com

- To examine potential adverse effects for V̇-Com™'s Quality Management System (QMS), 101 patients from a large community-based sleep medicine practice were recruited to examine the V̇-Com™ in the circuit in regard to effects on auto-titration algorithms (P90/955 pressure), usage time, leak and residual index (AHI).

- Each of the 101 participants were asked to give a written description of their experience with the V̇-Com™ during the 4 days of use. Of the total, 67% (n=67/101) responded and 77% (n=53/67) elected to continue use of the V̇-Com™ in their CPAP circuit long term.

Adherence data with V-com

Large DME in Midwest US independently examined 90-day adherence rates in new CPAP patients (n=100) using 4 hours 70% of nights as criteria and found V̇-Com™ yielded 12% increase in those meeting the criteria

Large DME in Southeast US provided struggling patients with a V̇-Com™ and found 30-day usage after V̇-Com™ was twice the 30-days before

Pressure Tolerance during CPAP Titration

V-Com™ improves pressure tolerance during in-lab CPAP titration in 91% of patients

- During collection of titration PSG data from June 2022 – February 2023 for TECSA and oral leak, sleep technologists were also allowed to add a V-Com™ to the PAP circuit of a patient with pressure intolerance to the point they were about to abort the titration study. During the time period of the study, sleep technologists identified 34 patients with such pressure intolerance. The V-Com™ alleviated the pressure intolerance such that the titration study could continue and be completed in 91% (n=31/34) of those patients.
- Statistics still in process. Manuscript preparation not begun

Eliminating Need for Chinstaps

- V̇-Com™ reduced the need for chinstraps in 85% (n=53/62) of 400 consecutive patients undergoing titration polysomnogram (PSG)

- The chinstrap was indicated (based on sleep technician assessment) in 16% (n=62/400) of titrations and V̇-Com™ was introduced first in all 62 cases. The V̇-Com™ avoided the need for a chinstrap in 85% (n=53/62) of cases, despite therapy pressure being further increased after the V̇-Com™ in many of these titration studies.

- Manuscript in preparation

Treatment-Emergent Central Sleep Apnea (TECSA)

- $\dot{V}$-Com™ improved treatment emergent central sleep apnea (TECSA) in 100% (n=17/17) and resolved 94% (16/17) of patients developing TECSA during 1000 consecutive titration PSGs
- With C-Flex+ **on** during titration study (n=500) there were 14 cases of TECSA (2.8%) and with C-Flex **off** (n=500) 3 cases of TECSA (0.6%)

- Our hypothesis was that TECSA resulted from augmented tidal volumes (V_t) and increased $\dot{V}_m$ from PAP therapy, particularly when IPAP greater than EPAP provides PS. While increased loop gain is likely involved, there must be some increase in $\dot{V}_m$ to reduce $ETCO_2$ below the apneic threshold.

Manuscript ready for submission

IPAP

EPAP

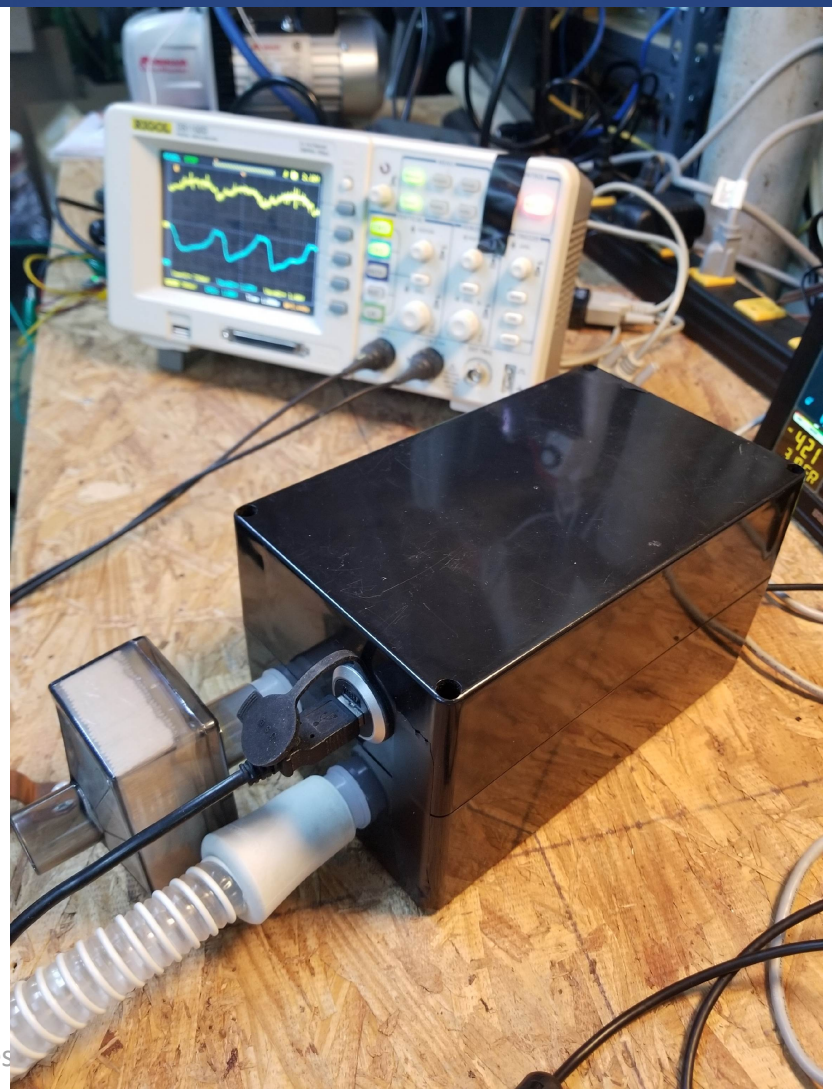
IPAP

EPAP

IPAP

EPAP

The Future of PAP Therapy



Let Patients Choose Comfort

- What constitutes sufficient evidence for use regarding comfort?
- Just like choosing a mask for comfort, let patients choose comfort with V̇-Com™
- Insist your patients always experience V-Com during PAP set-up and choose for themselves

V-COM™
CPAP made easy

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