

HYPERCAPNIA PREVENTS SLEEP APNEA

Colin Korlesky, Carly Hildebrandt, Chris Beglinger, Jon Elicson, Eric Howell

Client: John Webster PhD., Jerome Dempsey PhD.

Advisor: Jeremy Rogers

ABSTRACT

The goal of this project is to design a successful and novel alternative to continuous positive airway pressure (CPAP) therapy that incorporates dead space to treat central and obstructive sleep apneic events. Research has shown that the use of rebreathable dead space effectively increases CO₂ concentrations, induces moderate hypercapnic conditions, and effectively prevents apneic events. A hybrid, full face mask with an adjustable neoprene outer sleeve and rebreathable dead space attachments was fashioned. The design effectively induced moderate hypercapnic conditions as seen by an increase in fractional inspired CO₂ concentration up to 3%.

BACKGROUND

- Over 20 million Americans suffer from sleep apnea.^[1]
- Obstructive sleep apnea (OSA): Obstruction of the airway due to the collapse of soft tissue
- Central sleep apnea (CSA): Miscommunication between the central nervous system and respiratory stimuli.
- Complex sleep apnea (CompSA): Central apneas combined with airway obstructions.
- Continuous Positive Airway Pressure (CPAP): Therapy that forces pressurized air into the airway to prevent obstructions.
- Research has shown that moderate hypercapnic conditions (induced through dead space rebreathing) effectively treats airway obstruction and stabilizes central motor output.

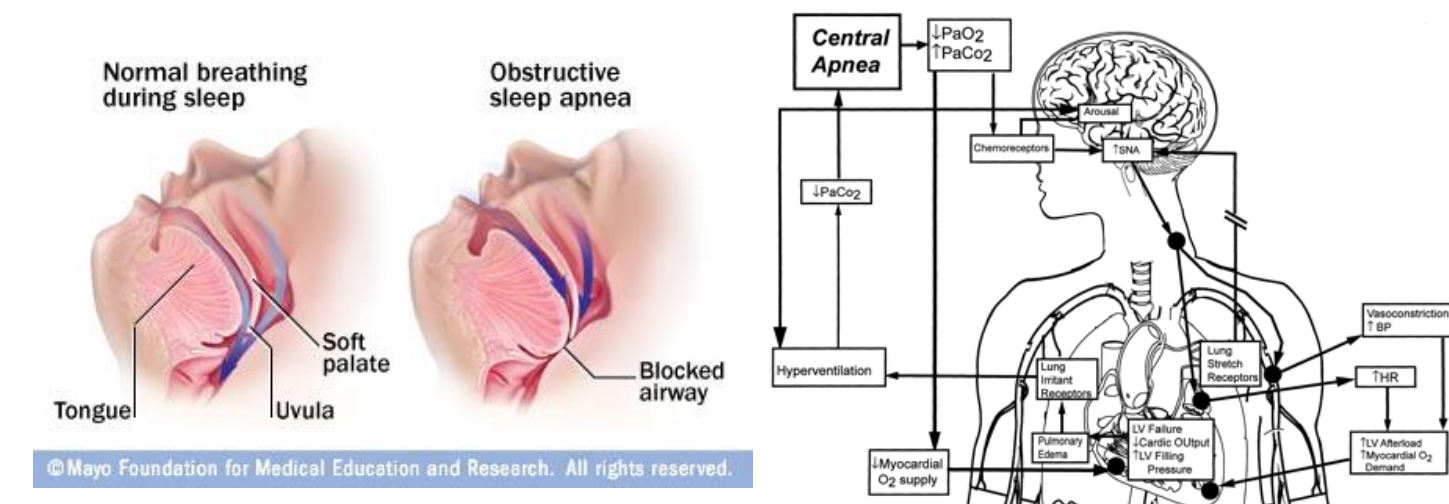


Figure 1: Diagram of obstructive sleep apnea (left) and central sleep apnea (right)^{[2] [3]}



Figure 2: Therapy options: CPAP machine and mask (left), and dead space rebreathing mask (right)^{[4] [5]}

MOTIVATION

PROBLEM STATEMENT: Design a device that:

- Monitors and maintains carbon dioxide concentration levels to prevent apneas
- Is easy to use, minimally invasive, and comfortable
- Is universally marketable

DESIGN SPECIFICATIONS

- Perform repeated nightly use and maintain extended functionality
- Be made of materials that are impermeable and nonreactive to carbon dioxide
- Facemask should cover the nose and mouth, while generating an effective seal
- Variable dead space attachments should be used to systematically increase dead space, resulting in effective treatment
- Easy to use and simple to operate
- Should be small, light weight, malleable, and soft to maximize comfort.
- Professionally crafted
- Comply with FDA regulations
- One product is needed

FINAL DESIGN

- Facemask:** Modified Elevation Training Mask 2.0
 - Inner silicon rubber mask
 - Durable, washable, outer neoprene skin with adjustable ear straps
 - Frontal opening for dead space attachment; lateral openings for sensors
 - Fits most adult head sizes
- Dead Space Tubing:** Bilge/Pump Hose
 - 1 1/8" diameter Rule hose
 - 12" long distinct segments with smooth mounting cuffs on both ends
 - Flexible, resistant to detergents
- Adapters:** Modified Quick Twist Adapters
 - Made of rigid acrylonitrile butadiene styrene (ABS) - Durable/Sterilizable
 - Allow for attachment to standard 1 1/8" diameter hose
 - Fittings allow for quick and simple connections



Figure 3: Elevation Training Mask 2.0

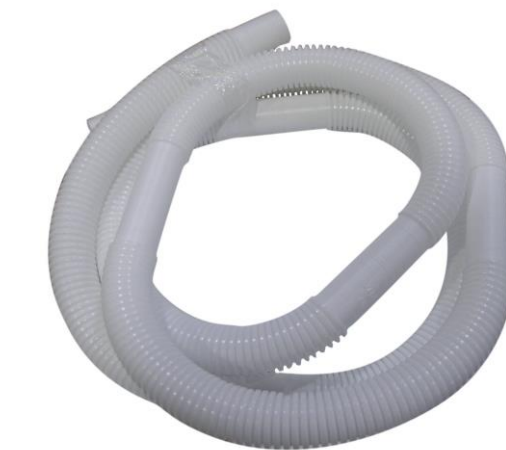


Figure 4: Bilge/Pump hose

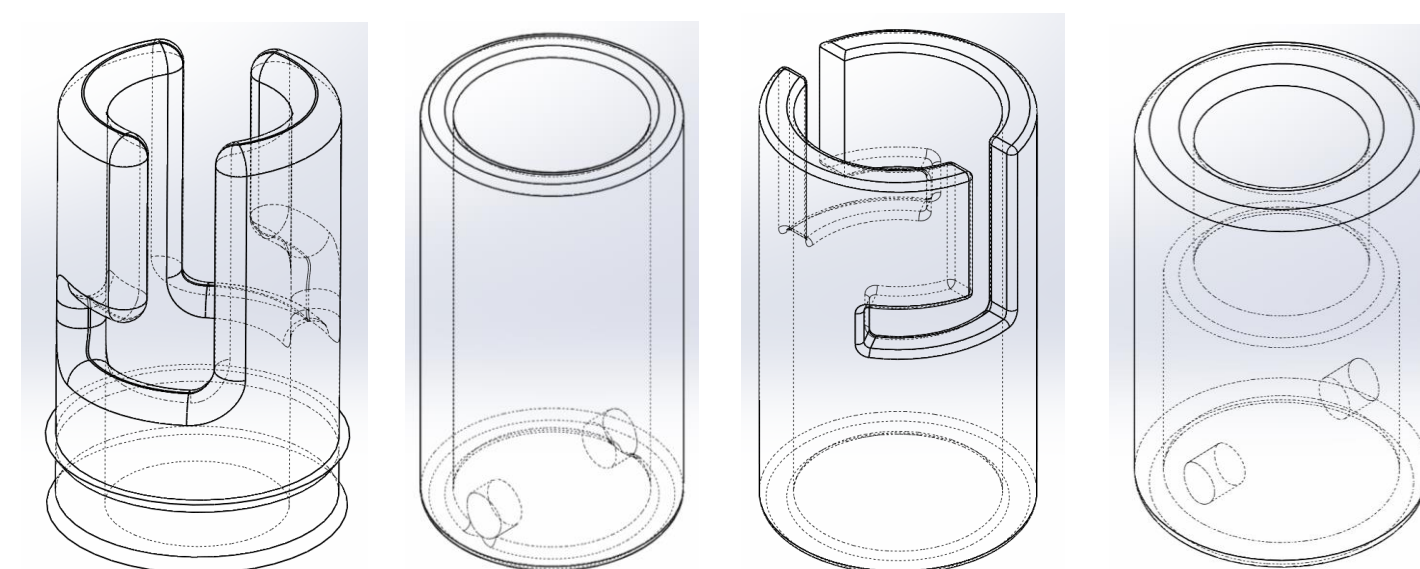


Figure 5: Solidworks of Modified Quick Twist Adapters



Figure 6: Final design

TESTING PROCEDURE

- Induced sleep apneic conditions in test subject
- Properly fit mask to the subject's face
- Attached pulse oximeter, carbon dioxide sensor, accelerometer, spirometer, and EEG (Figure 7)
- Performed two distinct tests:
 - Increasing carbon dioxide decreases apneic events:
 - Recorded the subject's apneic events per hour (APH) for:
 - No added dead space (control)
 - 450 mL dead space
 - 570 mL dead space
 - Prototype increased carbon dioxide concentration:
 - Monitored carbon dioxide sensor, pulse oximeter, and spirometer
 - No added dead space (control)
 - 380 mL dead space
 - 840 mL dead space

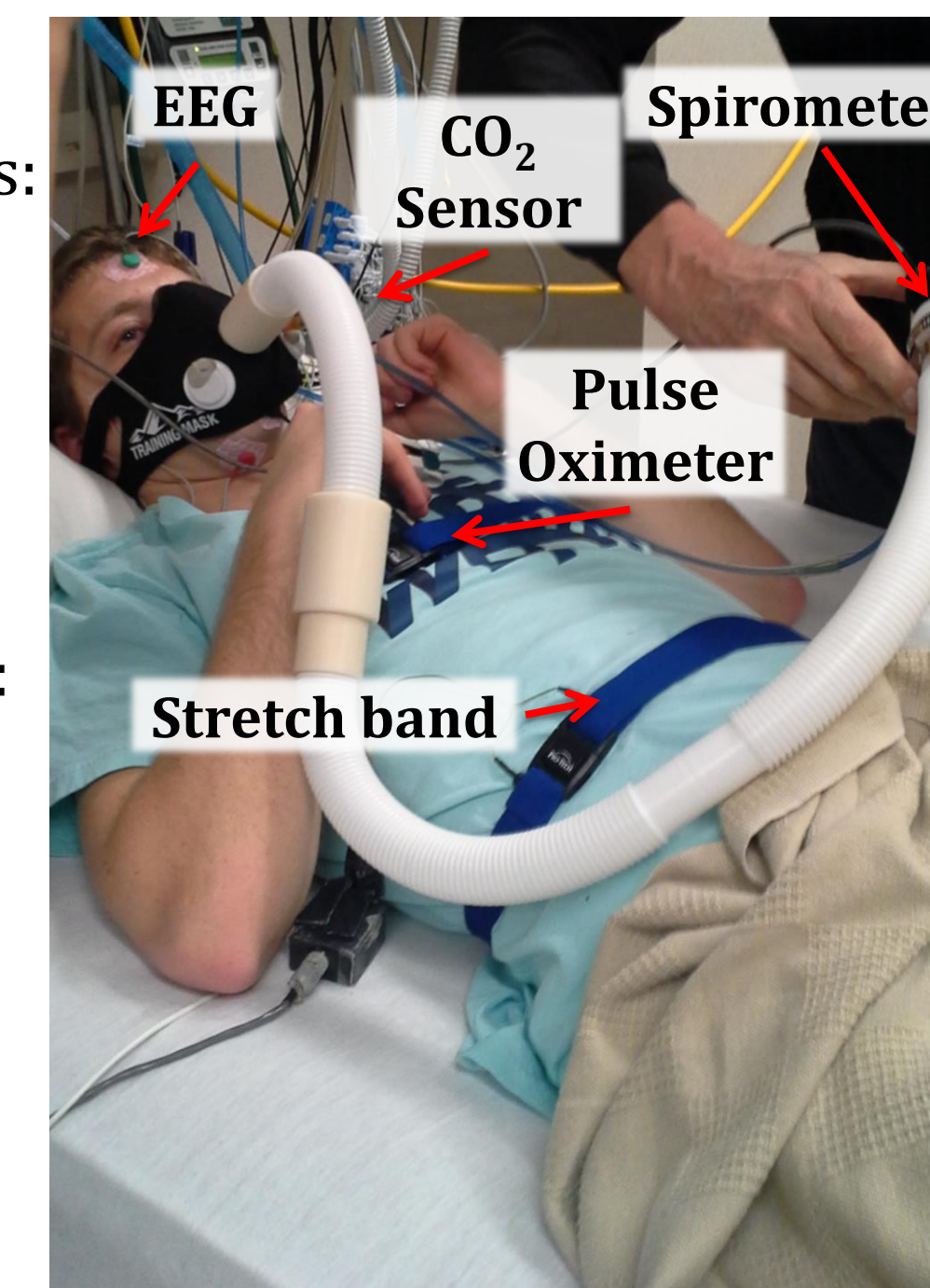


Figure 7: Testing environment

RESULTS & DISCUSSION

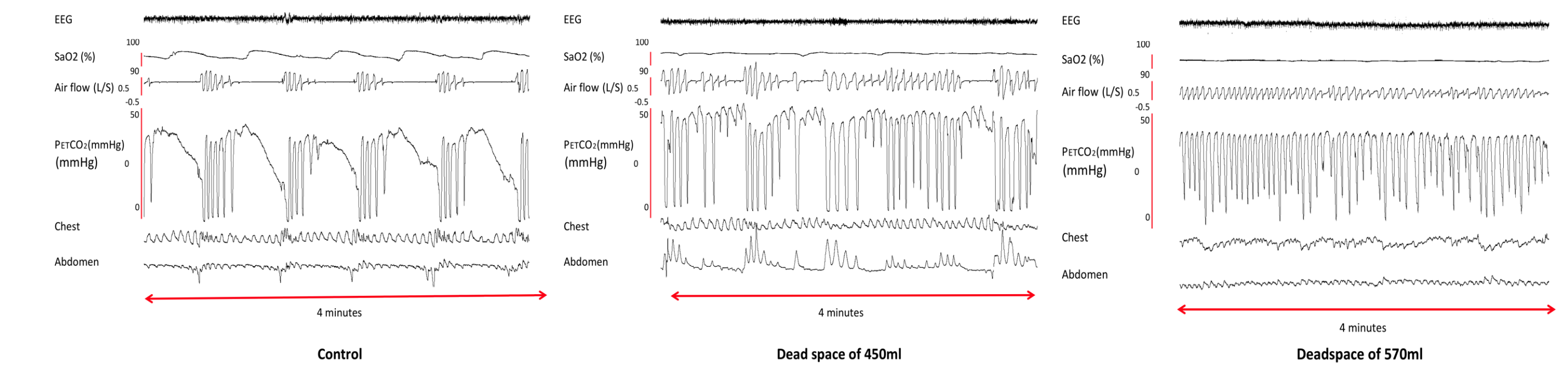


Figure 8: Graphical representation of EEG, carbon dioxide and oxygen concentrations, and inhalation and exhalation volumes for no added dead space (control), 450 mL, and 570 mL

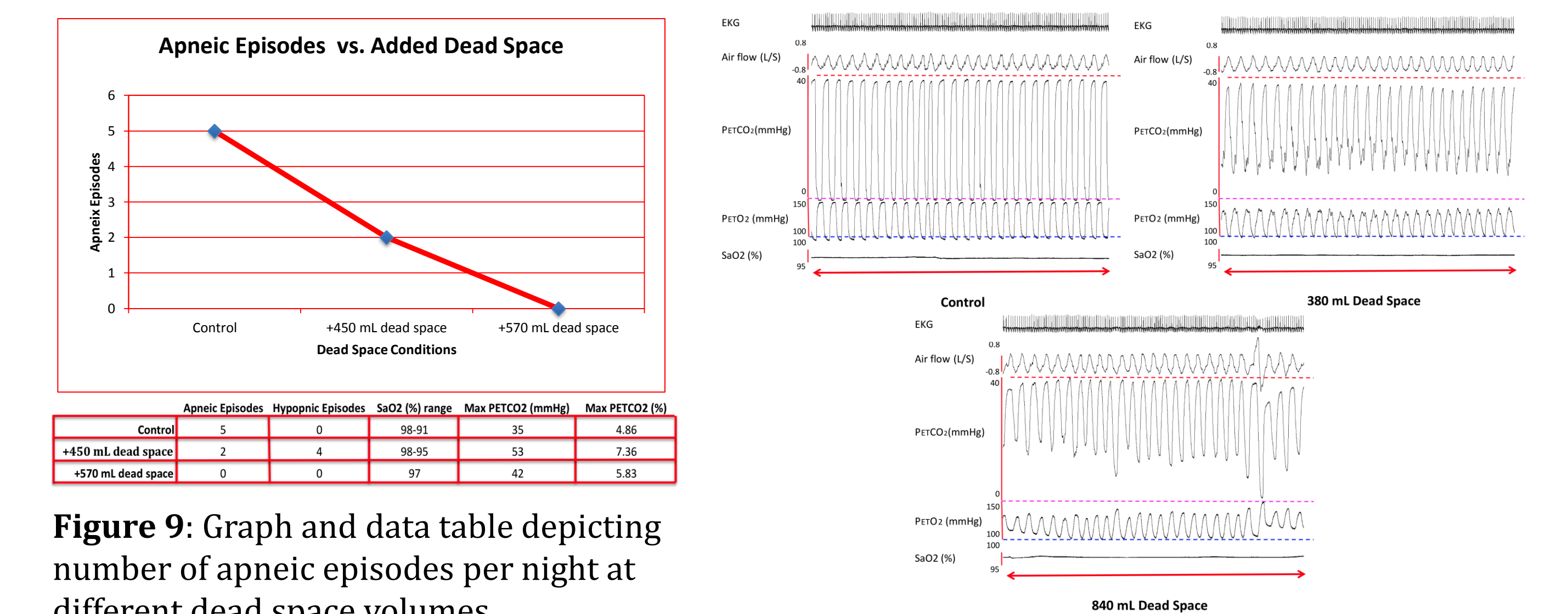


Figure 9: Graph and data table depicting number of apneic episodes per night at different dead space volumes.

Figure 10: Graphs of experimental data

DISCUSSION:

- Rebreathable dead space decreases apneic events per hour: (Figure 8, Figure 9)
 - Under isocapnic conditions:
 - 14 of 26 patients reduced AHI by more than 30%
 - Mean AHI dropped from 42 ± 5 to 13 ± 3 events/hour
 - 7 patients experienced an AHI of less than 10 events/hour
 - Under hypercapnic conditions:
 - 17 of 21 patients reduced AHI by 94 ± 3%
 - All 17 experienced less than 10 events/hour
- Prototype effectively increased carbon dioxide concentration: (Figure 10)
 - 380mL dead space increased fractional inspired CO₂ (FICO₂) by 1.5%
 - 840 mL dead space increased fractional inspired CO₂ (FICO₂) by 2.5-3%

FUTURE WORK

- Conduct more tests, with larger sample size
- Design smaller, sleeker adapters
- Modify facemask for even further adjustability and flexibility
- Utilize lighter weight materials (neoprene and lightweight plastics)
- Design a "Smart Dead Space" program

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