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The Journal of Pulmonary Technique





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Reference:
1. Svenningsen S, et al. COPD 2016;13(1):66-74.

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News

■ Winter 2017-2018

Firms Partner to Develop Inhaled Surfactant

Aerogen Pharma, a developer of innovative inhaled treatments for patients in critical care, and Lyomark Pharma, an established provider of high-quality medicines for the hospital market, are joining forces to develop a clinically superior treatment for Respiratory Distress Syndrome (RDS), a life-threatening condition of preterm infants associated with long-term lung health issues in survivors. AP-002 is a nasally inhaled surfactant based on a combination of Lyomark's Alveofact (bovine lung surfactant) and Aerogen's next generation "PDAP" delivery technology. The partners expect AP-002 to set a new standard in the treatment of RDS, since it will enable surfactant administration via the nose and complement current first line therapy with nasal continuous positive airway pressure ventilation (nCPAP). AP-002 is anticipated to reduce the need for sedation, invasive intubation and mechanical ventilation, all features of current surfactant treatment methods associated with adverse side effects and the potential to exacerbate chronic lung disease in preterm infants. The PDAP delivery system is a technical breakthrough based on patented enhancements to Aerogen's market-leading aerosol generator technology (www.aerogen.com), which effectively nebulizes surfactant and enables this potentially major advance in therapy. Alveofact is sold as an RDS treatment in 27 countries, with a proven record of safety and efficacy when administered by conventional instillation techniques and class-leading, three-year room temperature stability. Aerogen will adapt Alveofact for inhaled delivery, and the partners will work together to commercialise and distribute AP-002 around the world. AP-002 advanced to clinical trials. In a further development, Aerogen Pharma announced the initiation of a Phase 2 clinical study at three major

maternity hospitals in Australia. This trial will evaluate the safety and effectiveness of AP-002 relative to standard invasive surfactant administration in preterm infants with symptoms of RDS.

Details of this study are available at www.anzctr.org.au under Trial ID ACTRN12617001458325, and results are expected mid-2018. Aerogen Pharma is an Irish specialty pharmaceutical company developing inhaled products for quick, efficient, consistent and user-friendly treatment of critically ill patients in hospital acute care. Aerogen Pharma improves existing drugs by targeting them to the lung using a proprietary, high performance aerosol delivery system based on the market-leading nebuliser technology created by the Aerogen group. For more information, visit www.aerogen.com/aerogen-pharma/. Lyomark is a German pharmaceutical company specialised in niche proprietary and generic products and orphan drugs for rare diseases, presented as sterile injectable, lyophilized formulations in pre-filled syringes, vials and ampoules. Lyomark's Alveofact® lung surfactant has been in clinical use for twenty years as a treatment for neonatal RDS, with established safety and efficacy. For more information, visit www.lyomark.com.

New Patient Monitoring Unveiled

Medtronic plc has announced the US launch of the Vital Sync monitoring and clinical decision support (CDS) solution. The system is designed to simplify time-intensive patient care processes and help clinicians prevent or mitigate harmful and costly adverse events. The Vital Sync CDS solution combines remote monitoring software with wireless monitoring devices and a series of customizable CDS mobile applications to improve clinical protocol implementation and management of patients on medical-surgical floors and in the ICU. The Vital Sync CDS solution gathers patient physiological data directly from a variety of wireless and



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bedside devices, manufactured by Medtronic and third-parties. Analytics are continuously and automatically calculated, with customized alerts and notifications to help clinicians know as soon as possible if a patient is deteriorating. Respiratory therapy and nursing teams can remotely access patient data to make insightful assessments for more effective and earlier interventions. Patient data is accessed through the Vital Sync virtual patient monitoring platform. The solution also offers customizable tools, such as the Vital Sync Physiological Patch, a lightweight wireless device applied to the chest area that continuously collects and transmits physiological data, including heart rate, respiration rate, single-lead ECG and body position, to monitor vitals, facilitate pressure ulcer prevention protocols and help identify patient deterioration. The Vital Sync Weaning Readiness and SBT Monitoring App allows clinicians to continuously monitor and receive alerts indicating when a mechanically ventilated patient is ready to begin a weaning trial based on established clinical protocols. It also remotely tracks a patient's breathing pattern and other vitals through a spontaneous breathing trial so that clinicians can intervene if a patient falls outside predefined thresholds. The Vital Sync Early Warning Score App applies automated calculations based on published evidence for an early warning score to help give clinicians an earlier indication of patient deterioration. The app can detect subtle changes in patient deterioration using multiple parameters—enabling clinical intervention before a single parameter device would recognize a problem. Many common hospital-based patient safety issues are preventable. According to a recent report by the ECRI Institute, the top three patient safety concerns for healthcare organizations in 2017 are: insufficient management of electronic health record data, unrecognized patient deterioration and ineffective use of clinical decision support tools. The Vital Sync CDS solution was designed based on clinician input and clinical evidence to help hospitals avoid these and other patient safety challenges.

Study Demonstrates Device Choice Determines Asthma Control

A landmark real-world study involving more than 18,000 asthma patients has demonstrated superior asthma control with the AEROCHAMBER PLUS FLOW-VU antistatic Valved Holding Chamber (VHC) compared with other chamber devices. According to the study, published in *Pulmonary Therapy*, use of the AEROCHAMBER PLUS FLOW-VU antistatic chamber — from Monaghan Medical Corporation — resulted in delayed time to first exacerbation, fewer asthma-related emergency department visits, and lower exacerbation-related costs than control chambers. Asthma is a common respiratory condition that affects an estimated 24.6 million people in the United States. Almost half of them, including nearly 3 million children, experience one or more asthma attack in a year. As opposed to systemic medications, inhalation is the recommended way to administer asthma medications because it directly targets the drug to the lungs while reducing potential side effects. Inhaled corticosteroids and bronchodilators administered by MDIs are the mainstay of long-term asthma treatment, the goals of which are to improve symptoms and prevent the occurrence of exacerbations. Poor inhaler operation by users is common, resulting in less of the delivered drug reaching the lungs. Instead, much of it is deposited on the back of the throat (oropharyngeal deposition) and then swallowed. Research shows that between 28% and 68% of patients do not use inhalers well enough to benefit from prescribed medication. In addition, 25% of costs associated with inhalers is wasted due to poor inhaler technique.

Chambers are designed to reduce oropharyngeal deposition by changing the particle size distribution of the inhaled aerosol, and by holding the aerosol in the chamber until the patient is ready to inhale, which reduces the need for good coordination between inhalation and inhaler actuation. Effectiveness of these devices can be adversely affected by the design, including the chamber electrostatic charge, a commonly reported cause of inconsistent medication delivery. Global respiratory guidelines recommend the use of chambers to improve MDI drug delivery. American Thoracic Society and American Association for Respiratory Care Clinical Practice Guidelines state that the addition of a chamber is recommended and helpful. Research also indicates that patients who use a chamber with an MDI have better asthma control than those using an MDI alone. In this new study, Dr Chakkarin Burudpakdee (QuintilesIMS, Fairfax, VA, USA) and colleagues compared the effects of the antistatic AEROCHAMBER PLUS FLOW-VU and control chambers on treatment outcomes, resource use, and healthcare costs in a real-world asthma population. More than 18,000 patients were included from an adjudicated claims database containing medical and pharmacy claims for more than 150 million U.S. health plan members. The analysis showed that among patients with at least 30 days of follow-up, those using the AEROCHAMBER device experienced a delay in the time to first exacerbation and had fewer asthma-related emergency room visits. In addition, exacerbation-related costs were lower when compared to those using the control (non-antistatic) chambers. A trend toward lower exacerbation rates per patient for the AEROCHAMBER PLUS FLOW-VU was sustained throughout the 12 months of the study.

Significant Cost Reduction in COPD Care

The Aerobika Oscillating Positive Expiratory Pressure (OPEP) device (Monaghan Medical Corporation) is a cost-effective treatment option in the management of COPD exacerbations, according to a study published October 20 in the *International Journal of COPD*. This study, which used data from the published literature and national fee schedules to model the cost-effectiveness of the Aerobika OPEP device, shows that it provides both clinical benefit and direct medical cost savings in a post-exacerbation care COPD population. COPD is a major (and growing) source of morbidity, mortality and healthcare utilization, with hospitalization for acute exacerbations being the biggest cost driver. Once a patient experiences an exacerbation, the risk of further exacerbation is increased two- to four-fold, and many patients experience two or three exacerbations every year. As many as one in five patients discharged from hospital following an exacerbation are re-admitted within 30 days. The economic burden on the healthcare system associated with COPD is significant; in the US alone, the cost of COPD in 2010 was estimated to be US \$50 billion; \$30 billion in direct healthcare expenditure, with the remainder accounted for by indirect costs such as productivity losses and costs to families. Approximately half of the direct costs could be accounted for by hospital care for COPD exacerbations, which supports the GOLD guideline treatment goals of minimizing the negative impact of exacerbations and preventing recurrences. Healthcare systems in many countries acknowledge the problem, and policies are now being put in place to try to address it; the US Medicare Hospital Readmission Reduction Program penalizes hospitals for excess 30-day, all-cause readmissions after a hospitalization for an acute exacerbation of COPD. The Aerobika OPEP device is a drug-free, handheld mechanical oscillating positive expiratory pressure (OPEP) device that has been designed to address the structural



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and functional challenges in the airways of patients with COPD. When the patient exhales through the device, it helps to expand the airways, loosen and expel mucus from the lungs and may also enhance drug deposition. It has been shown to improve lung function, exercise capacity and quality of life in COPD patients, and a recent real-world study showed that the device reduced exacerbation rates in patients during the critical 30-day post-exacerbation period. Using data from the latter study to provide real-world input, the authors of this current analysis showed cost savings (\$553 per patient) and improved outcomes (equivalent to 6 fewer exacerbations per 100 patients per year) with the Aerobika OPEP device compared with no OPEP/PEP use, and concluded that the device provides cost-effective treatment for post-exacerbation COPD patients. The authors also used various scenarios to investigate the likelihood of the benefit continuing over a full year, and predicted further clinical and cost benefits (21 exacerbations per 100 patients per year; cost savings of \$1,952 per patient). Author Dominic Coppola, MBA, RRT, FAARC, Vice President Clinical Strategy and Development noted, "Our model provides evidence of clinical and cost benefits of the Aerobika OPEP device in that critical 30-day period following an exacerbation. Given the high burden of COPD — in particular, costs relating to exacerbations — in the US population, we would expect that even a small benefit would have a significant impact on the healthcare system". He went on to say that, although further studies would be needed to validate the long-term effectiveness, these data also give a good indication that the benefits will be sustained with long-term use.

Trial Approved In Canada

Novoteris, LLC, a clinical stage medical device and pharmaceutical developer focused on innovative nitric oxide gas applications, announced that the Therapeutic Products Directorate of Health Canada has cleared an investigator sponsored, pilot clinical trial application exploring the treatment of Non-Tuberculous Mycobacteria (NTM) with Novoteris' Thiolanox inhaled nitric oxide gas, using its unique computerized trace-gas delivery system. This single center open label trial will recruit 10 subjects to the Vancouver clinical site. This trial will enable the testing of nitric oxide in patients who have this debilitating disease and who are excluded from the Novoteris Phase 2 placebo controlled trial recruiting patients with Cystic Fibrosis (CF) in North America. Novoteris has demonstrated the broad-spectrum anti-microbial property of nitric oxide effectiveness against mycobacterium both with in-vitro studies and a 4.5 log decrease in sputum bacteria levels in two human subjects with Mycobacterium abscessus that were treated in its pilot clinical trial of patients with Cystic Fibrosis in Europe. Gaseous nitric oxide's potent antimicrobial properties, lack of bacterial resistance, and small molecule penetration capabilities could provide a promising alternative, non-antibiotic approach to treating infections in people living with this disease. "The clearances by Health Canada will enable us to expand our work with this novel therapy to a wider range of people with an exceptional need for more effective antimicrobials and represents another important opportunity for Novoteris," stated Alex Stenzler, President of Novoteris.

Three-in-one Benefits with Adapter

Why choose between oxygen, nebulized medicine, and patient comfort, when you can have all three? Administering steady levels of oxygen and medicine can be frustrating, as well as uncomfortable to your patients. The multi-use nebulizer oxygen delivery adapter called Munoda is designed to solve many of

the challenges respiratory therapist face every day, and it puts patient comfort at the forefront while also providing benefits at the clinical and facility levels. Seamlessly connecting to standard oxygen masks and tubing, the Munoda Respiratory Adapter enables the simultaneous delivery of oxygen and nebulized medication. Allowing multiple configurations, this adapter provides respiratory therapists and EMTs with a versatile solution for a wide range of treatments. Visit Conmed.com.

Opioids Linked to Hospital-Acquired Pneumonia

Patients prescribed fentanyl, morphine, or codeine in the 100 days before being hospitalized have an increased risk for pneumonia while in the hospital, results of a new study suggest. The relationship is probably due of immune suppression and not respiratory depression, the researchers speculate. "This is just a signal finding, but it makes me think that in vulnerable patients, such as those who are already immune suppressed, including HIV patients and those on biologics, we might want to weigh immunosuppressive effects of opioids when we make decisions about how we prescribe," said lead researcher, Andrea Rubinstein, MD, Permanente Medical Group, Santa Rosa, California. Dr Rubinstein discussed her research at the American Academy of Pain Medicine (AAPM) 2017 Annual Meeting. The new study examined 40,403 admissions of patients aged 18 to 70 years to the Kaiser Permanente health system over a period of about 4 years. The Kaiser system includes 19 hospitals in northern California and, at the time of the study, had 3.9 million patients. Researchers looked at opioids (at least a 60-day supply) prescribed in the 100 days before the hospital admission. They grouped patients into "no opioid"; "fentanyl, codeine, morphine"; and "other opioid," which could include hydrocodone, oxycodone, or hydromorphone. They also looked at whether an opioid was prescribed during the first 2 days of the hospital stay. The outcome was hospital-acquired pneumonia (HAP), a condition reportable to the Centers for Disease Control and Prevention. Here, researchers assessed HAP that developed on days 3 to 10 of the hospital stay.

Device For Airway Function Approved

Thorasys Thoracic Medical Systems Inc. has announced that the US Food and Drug Administration (FDA) has approved the sale and the distribution of the tremoflo C-100 Airwave Oscillometry System (AOS), a medical device that offers fast, easy assessment of large and small airway function. Measurements are obtained during tidal breathing and without patient effort, which makes it a suitable device for a wide range of patients. "Today's approval is the payoff of more than seven years of persistent hard work by the Thorasys team to develop the innovative tremoflo C-100." said Thorasys co-founder, president & co-CEO, Thomas F. Schuessler. Thorasys Thoracic Medical Systems Inc. is a respiratory medical device company based in Montreal, Quebec, Canada. Thorasys applies cutting edge research and technology to the development of products for pulmonary assessment. It designs, manufactures and commercializes pulmonary function test equipment for the assessment and monitoring of lung diseases such as Asthma and COPD. The company is currently focused on expanding. You can find out more at www.thorasys.com.

New Mask Conforms to Infants' Faces

Respiralogics' announces the US release of the Babi.Plus nMask precisely designed to easily conform to an infant's face, facilitating a good seal for optimal ventilation during resuscitation and non-invasive support. The soft, brushed

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silicone material minimizes skin irritation. The circular design of the nMask provides a comfortable anatomical seal for the very low birth weight infants through toddlers. The clear nMask provides a good view of the patient/mask interface to ensure proper fit and size. The Babi.Plus nMask is offered in 6 sizes to accommodate the ELBW infant through small pediatric patient. Integral 15mm connector with two level barb design at the inlet of the nMask allows for easier attachment and better fixation. Available in 25mm, 30 mm, 35 mm, 40 mm, 45 mm and 50 mm masks; each nMask is individually packaged and ready for use with resuscitation bag or t-piece resuscitator system. The Babi.Plus nMask can be used in all neonatal critical care units, delivery rooms, pediatric critical care units and special procedure units. Respiralogics specializes in providing tools to meet the unique needs of respiratory patients. We listen to our customers and use that knowledge to assist in development and support of specialty products to benefit patients and clinicians. We have joined with leading specialty respiratory distributors across the USA to provide expert local assistance and the training required for successful implementation.

Mobile Vest Unveiled

International Biophysics Corporation, a global medical device manufacturer and the pioneer of mechanical oscillation vest therapy, has introduced its next generation AffloVest fully mobile respiratory HFCWO (High Frequency Chest Wall Oscillation) airway clearance vest. The AffloVest is battery-operated and uses Direct Dynamic Oscillation technology, which closely mimics hand CPT (Chest Physical Therapy) to help mobilize and clear secretions from the lungs, and allows for full freedom of mobility during treatment. Doctors prescribe AffloVest for patients across a wide range of ages who have severe respiratory diseases such as bronchiectasis, cystic fibrosis, and certain neuromuscular diseases. This next generation AffloVest, which began shipping September 1, is much lighter, quieter, and more efficient, with a smaller profile battery and long-life, state-of-the-art motors, offering improved patient ease of use. The new AffloVest is on average 2 pounds lighter (more than 20% less weight) than the previous version — which was already by far the lightest mobile, mechanical oscillation vest on the market. The new AffloVest also uses streamlined components and tailored styling for a sleeker, slimmer fit. International Biophysics founder and CEO, H. David Shockley said: “With this next generation AffloVest, we have once again listened to patients and clinicians to remain the innovator and leader in mechanical oscillation vest therapy. AffloVest was already the lightest fully mobile vest on the market, and our new version is even lighter. Patient comfort and ease of use during treatment is very important, and weight is the major contributing factor to comfortable, sustainable mobile therapy. Simply put, if it's too heavy and difficult to use, patients are not going to like it. AffloVest is light and easy to use compared to other vests.” In April 2017, Hill-Rom announced that it was introducing an Afflo-style vest airway clearance device also using mechanical oscillation technology. According to their product literature, that vest will weigh 5 lbs. (38%) heavier than the AffloVest, is restricted to patients 15 years of age and older (in contrast to the AffloVest, which is not age-restricted), and will be available in only one size, unlike the AffloVest, which is available in many sizes to facilitate proper fit for anatomically-targeted treatment. As Hill-Rom's product is not yet commercially available on the market, International Biophysics is not able to independently validate Hill-Rom's promotional claims. Shockley added, “We welcome competition and view imitation as validation that our fully mobile mechanical

oscillation is the gold standard for mobile mechanical oscillation therapy. We have thousands of AffloVests already in use and, more importantly, we have clinician data showing lung function improvement with patients. AffloVest is the original, proven innovator in mechanical oscillation vest airway clearance therapy.” International Biophysics brings to market innovative, disruptive medical devices and technologies aimed at improving treatment therapies and patient outcomes. Centered on a precision ISO 13485 certified, FDA registered quality controlled USA manufacturing facility in Austin, Texas, International Biophysics has a 25-year pedigree of successful medical product and technology launches around the globe.

New Adapter for Soft Mist Inhaler Medication Delivery

ODAPT Soft Mist Adapter has received FDA approval and is now available in the United States. ODAPT is the only product created specifically for use with the Soft Mist family of inhaled medications. Designed by a Respiratory Therapist to provide clinicians and patients a solution for face mask and tracheostomy application of Soft Mist Inhalers (SMI). ODAPT aids in the delivery of soft mist inhaled medications for pediatric and elderly patients where a face mask is required. As well, it expands the delivery of soft mist for tracheostomy patients of whom in the past had no delivery option. Respiralogics and McArthur Medical will introduce ODAPT to the US market during the 2017 AARC meeting, booth 212. McArthur Medical produces the ODAPT family of products. McArthur Medical is a company focused on the development of respiratory innovations. Respiralogics is a provider of innovative products for hospital, emergency, home and specialty care.

Single Inhaler Triple Therapy Effective for COPD

A single inhaler triple therapy provides clinical benefits superior to those of the muscarinic antagonist tiotropium alone in patients with symptomatic chronic obstructive pulmonary disease (COPD), according to the TRINITY trial. “Triple therapy now has an evidence-base and is effective,” Dr Jorgen Vestbo from the University of Manchester, UK, said. “It works better in patients with higher eosinophils and it also signals that there are patients who benefit less from triple therapy (or any regimen including an inhaled corticosteroid).” Most guidelines recommend triple therapy with an inhaled corticosteroid, a long-acting beta2 agonist and a long-acting muscarinic antagonist in patients with exacerbations despite initial treatment with either a long-acting muscarinic antagonist or an inhaled corticosteroid and long-acting beta2 agonist. But few studies have addressed the added value of triple therapy in this setting, Dr. Vestbo and colleagues said. The team evaluated the effects of three different treatment approaches in their study of nearly 2,700 patients with symptomatic COPD: fixed triple therapy with a single inhaler containing extrafine formulations of the inhaled corticosteroid beclomethasone dipropionate (BDP), the long-acting beta2 agonist formoterol fumarate (FF) and the long-acting muscarinic antagonist glycopyrronium bromide (GB); tiotropium monotherapy; and open triple therapy with BDP/FF in one inhaler and tiotropium in a second inhaler. Compliance was high (about 94%) for all three treatments. Moderate-to-severe COPD exacerbations were significantly less common with fixed triple therapy (0.46 per patient per year) and open triple therapy (0.45 per patient per year) than with tiotropium monotherapy (0.57 per patient per year). The benefits of the two triple therapies were even greater relative to tiotropium monotherapy in the subgroups with higher eosinophil concentrations and in the subgroup of patients with more than one exacerbation in

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the previous 12 months. The time to first moderate-to-severe exacerbation was significantly extended with fixed triple and open triple therapies versus tiotropium. Pre-dose FEV1 at week 52 improved from baseline by 0.082 L with fixed triple therapy and by 0.085 L with open triple therapy, but only by 0.021 L with tiotropium. Rescue medication use was similar in the fixed triple and open triple groups, whereas patients receiving tiotropium required more rescue medication. Adverse events, most of them mild or moderate in severity, occurred with similar frequency in the three treatment groups. Dr Vestbo suggested that fixed triple therapy might be especially beneficial “in patients who continue to have exacerbations on mono or dual therapy and who are likely to respond to inhaled corticosteroids, ie, having asthma-like exacerbations, not being permanently colonized with bacteria, and/or having blood eosinophils above, e.g., 300 per mcL ... Finally, there is likely to be a fixed triple combination on the market in the near future, and this should make treatment of severe COPD a lot simpler for patients,” he said.

Pediatric Influenza Deaths Concentrated in Unvaccinated Kids

Most of the children and adolescents who died from influenza in the United States between 2010 and 2014 were unvaccinated, a new case cohort analysis has found. “Among deaths in children with known vaccination status, children who died had lower vaccination uptake for all age categories, seasons, and infecting influenza virus types than the [National Immunization Survey–Flu (NIS-Flu)] cohort,” the researchers write. Brendan Flannery, PhD, from the Influenza Division and Immunization Services Division at the Centers for Disease Control and Prevention in Atlanta, Georgia, and colleagues conducted the report. The study included deaths in US residents younger than 18 years who had laboratory-confirmed influenza virus infection reported to the Influenza-Associated Pediatric Mortality Surveillance System. The study included children who were aged at least 6 months on November 1 of the influenza season during which the child died, who were eligible to receive at least one dose of seasonal influenza vaccine, and for whom a complete medical history was available. The investigators used three comparison cohorts: NIS-Flu, the National Health Interview Survey, and the MarketScan Commercial Claims and Encounters database. During the study period, vaccination status was determined for 291 of 358 laboratory-confirmed influenza-associated pediatric deaths. Of those, 75 (26%) received seasonal influenza vaccination at least 14 days before they became ill. Vaccine type was known for 62 cases: 12 (19%) children received live-attenuated influenza vaccine and 50 (81%) received inactivated influenza vaccines. In contrast, overall vaccination coverage was 48% among the NIS-Flu cohorts. The researchers estimate that vaccine effectiveness against pediatric death was 65% (95% confidence interval [CI], 54% – 74%). Vaccine effectiveness ranged from 54% during the 2010 to 2011 season to 80% during the mild 2011 to 2012 season, when the number of pediatric deaths was the lowest. Vaccine effectiveness point estimates against death associated with influenza A virus (66%) and influenza B virus (62%) were similar. The authors note that 53% of the deaths in children with known vaccination status occurred among those with one or more underlying high-risk medical conditions. Of those, 47 (31%) were vaccinated. The researchers did find that children with one or more high-risk conditions were more likely to be vaccinated than their peers without such conditions. Specifically, the vaccination rate was 20% among children without high-risk conditions, 31% among children with one or more high-risk condition, and 37% among children with two or more high-risk conditions. Overall,

however, less than half of all individuals in high-risk categories were vaccinated, the researchers note.

Device Receives Innovative Technology Designation

Monaghan Medical Corporation announced its Aerobika Oscillating Positive Expiratory Pressure (OPEP) device has received a 2017 Innovative Technology designation from Vizient, Inc., the largest member-driven health care performance improvement company in the country. The designation was based on direct feedback from hospital experts who interacted with the Aerobika OPEP device at the Vizient Innovative Technology Exchange in Denver. The device is a drug-free, handheld mechanical oscillating positive expiratory pressure (OPEP) device that has been designed to address the structural and functional challenges in the airways of patients with COPD. When the patient exhales through the device, it helps to expand the airways, loosen and expel mucus from the lungs and may also enhance drug deposition. It has been shown to improve lung function, exercise capacity and quality of life in COPD patients, and a real-world study showed that the device reduced exacerbation rates in patients during the critical 30-day post-exacerbation period. These improved outcomes (equivalent to 6 fewer exacerbations per 100 patients per year) equate to a cost savings of \$553 per patient with Aerobika compared with no OPEP/PEP use, making the device a cost-effective treatment for COPD patients. “We are extremely pleased to have been awarded this prestigious recognition from Vizient,” said Dominic Coppolo, MBA, RRT, FAARC, Vice President Clinical Strategy and Development. “Our device was recommended by Vizient members, which is a validation of all of the design and clinical work we have done to support our customers. We are the only OPEP device to have received this designation at this year’s Innovative Technology Exchange, and are proud it was recognized to deliver improved outcomes and enhanced safety.” “Based on feedback from attendees at the Vizient Innovative Technology Exchange, it was determined that the Aerobika OPEP device should be recognized with an Innovative Technology designation. This designation will be noted in our online member contract catalog. Congratulations to Monaghan Medical Corporation on receiving this status,” said Debbie Archer, director of procurement and Vizient Innovative Technology Program lead. Vizient represents a diverse membership base that includes academic medical centers, pediatric facilities, community hospitals, integrated health delivery networks and non-acute health care providers and represents more than \$100 billion in annual purchasing volume. Through its Innovative Technology Program, Vizient works with member-led councils and task forces to review potentially innovative products. If it is determined that a product is innovative, Vizient may award a contract outside of the competitive bid cycle.

Let There Be Light On Patients

Neotech Products has announced the release of their newest product, the NeoGlo Transilluminator. The NeoGlo Transilluminator is a light source that transmits light through tissues to aid in the examination of patients. It is used to find veins, arteries, and other internal structures. This innovative vein finder features LED lights that are cool to the touch for patient safety. It has multiple light settings for user preference including forward facing white lights, upward facing white lights, and upward facing red lights. It’s compact size and ergonomic design was engineered with clinician comfort in mind. The NeoGlo is available in five colors, blue, rose, white, silver, and



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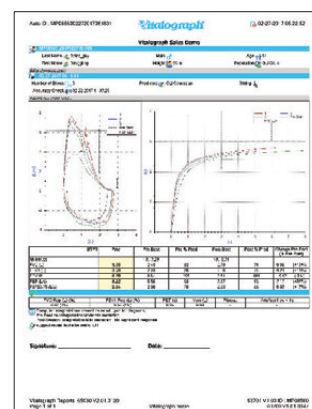
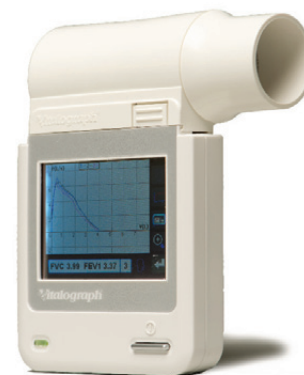
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black. It is powered by a single AA battery and is engineered to shut off before the lights become ineffective. "We like to say 'designed with the clinician in mind,' said Neotech Products President, Craig McCrary. "The truth is, clinical input was key to the development. A doctor presented his original idea to Neotech two years ago. Respiratory Therapists and Registered Nurses then added their input. They told us what they'd like to see in a transilluminator. Next, our engineers showed us what they could do. And together, we developed the NeoGlo into an exceptional and innovative vein finder. "Our mold makers also offered input," McCrary continues. "Before going to production, we modified the mold to add the lanyard clip. Which is a simple feature that adds value for the clinicians. No other single device offers the features we do for the price; under \$100. Plus the NeoGlo is made in USA."

Ventilating Mask Goes Portable

Pinnacle Sciences, a UK-based diverse research and development company, has released news of its latest development, the highly portable, battery-operated Ventilating Mask. A market first, the device is unique in that it provides many modes of therapies — and as opposed to conventional devices that require a tube to connect from a power unit, this device fits directly on the mask completely eliminating dead space. This allows for lower pressures to be used, which the company claims will mean significantly increased comfort for the patient. The device can also be used with a tube, be clothes mounted, or put in a pocket. The device line, expected to cost around \$330 with a bundled mask, is not just a CPAP or bi-level device. Variants of the line include full ventilation, cough assistance, as well as high-frequency modes (HFO). Later models will also allow

for invasive ventilation options, at similar pricing. Wolf Hayek, President and CEO of Pinnacle Sciences, commented, "We are very proud of this new patented technology, which is set to shake the CPAP/Bi-Level/Cough Assistance and Ventilator markets to the core. The proposed price point of this device, we believe, will shake out the weaker players in the respiratory and sleep markets, and send a shock wave through the industry as a whole. The phrase game changer is often thrown around. This technology will likely end the game for some, and allow others to play it in a completely different way altogether." Hayek added, "DME companies throughout the United States have had to deal with the reality of vastly decreased reimbursement for services and products they provide, often providing those services at a loss. We hope to change that. The line-up of products isn't just aimed at the sleep market, which today is oversubscribed as well as over prescribed — we see this technology as an eventual replacement of a whole host of products for use both in the hospital and the home, at a price point that does away with servicing and other costs associated with competing products. The devices themselves — we see as disposables — for the cough, ventilation and other respiratory arenas. It's cheaper, more versatile, and just so much more convenient." Pinnacle Sciences, a Hayek company, specializes in the development of innovative technologies in the health care, military and transport sectors. For further information, visit www.VentilatingMask.com.

Anti-Inflammatory Interleukin Inhibitor Reduces Lung Cancer

A secondary finding from a large clinical trial in patients with atherosclerosis has shown that reducing systemic inflammation with an interleukin-1beta inhibitor drug significantly reduced lung cancer incidence, as well as total cancer and lung cancer mortality. The drug, canakinumab (Ilaris, Novartis), is already marketed for the treatment of rare autoimmune disease. The Canakinumab Anti-inflammatory Thrombosis Outcomes Study (CANTOS) has been making headlines, after results from the trial were presented at the European Society of Cardiology (ESC) Congress 2017 and were simultaneously published in the New England Journal of Medicine. The primary finding was a reduction in major cardiovascular events, despite there being no effect on cholesterol. One eminent cardiologist hailed the results were hailed as a "historic moment...as it shows a new direction." But there was another remarkable finding — an exploratory analysis showed a marked reduction in the incidence of lung cancer, as well as lung cancer mortality and total cancer mortality. After a median follow-up of 3.7 years, there was a 67% reduction in incident lung cancer ($P = .00008$) and a clear dose-dependent risk reduction in cancer mortality, which reached 51% with the highest dose of the drug ($P = .0009$). "The data are exciting because they point to the possibility of slowing the progression of certain cancers," lead author Paul M. Ridker, MD, from Brigham and Women's Hospital, Boston, Massachusetts, commented in a statement. It has previously been shown that the use of aspirin to reduce inflammation lowers the risk for cancer death, although these effects are seen after a decade or more of long-term use. The effects with canakinumab occurred over a much shorter time course, the authors note.

COPD: 3.2 Million Deaths Worldwide in 2015

Although overall prevalence and death rates for asthma and chronic obstructive pulmonary disease (COPD) declined between 1990 and 2015, population growth and aging have driven up worldwide numbers for these lung conditions, according to estimates from the 2015 Global Burden of Disease (GBD)

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Study. Asthma remains the most common chronic respiratory disease globally, but in 2015, COPD caused an estimated eight times more deaths, at 3.2 million vs 0.40 million. The GBD collaborators call for data-informed policy making and strategic interventions to decrease the burden of these noncommunicable diseases and improve care. They note that reducing the global toll will require action beyond smoking cessation, including a reduction in air pollutants in the community, home, and workplace. These include cooking fuel smoke, asbestos, diesel fumes, arsenic, and benzene. "COPD and asthma are important contributors to the burden of non-communicable disease," write Theo Vos, MD, PhD, professor of global health at the Institute for Health Metrics and Evaluation at the University of Washington, Seattle, and colleagues. "Although much of the burden is either preventable or treatable with affordable interventions, these diseases have received less attention than other prominent non-communicable diseases like cardiovascular disease, cancer, or diabetes." Dr Vos and associates also stress the need for the collection of up-to-date population-based information to improve access and quality of care. They caution that because of global variations in disease definitions and data quality, the study's estimates are somewhat uncertain, and hence the report includes uncertainty intervals (UIs) with its figures. The estimates are based on published papers, unpublished reports, surveys in the GBD's Global Health Data Exchange repository, and US healthcare services data. Deaths caused by COPD rose by 11.6% (95% UI, 5.5% – 19.8%) during the 25-year study, going from 2.8 million in 1990 to 3.2 million (95% UI, 3.1 million – 3.3 million) in 2015. Cases increased by 44.2% (95% UI, 41.7% – 46.6%), going from 121 million to 174.5 million (95% UI, 160.2 million – 189.0 million). In terms of prevalence, the greatest decrease in age-standardized COPD prevalence occurred in countries in the middle and high-middle quintiles of the sociodemographic development index, a measure calculated on lagged distributed income per capita, average years of education after age 15 years, and total fertility rate. In 2015, COPD caused 2.6% of global disability-adjusted life years (DALYs), a measure of overall disease burden based on the number of years lost as a result of ill-health, disability, or early death. Asthma accounted for 1.1%. During the study, asthma deaths declined by an estimated 26.2% from 0.55 million to 0.40 million, but asthma prevalence increased by 12.6%, going from 318.2 million to 358.2 million cases (95% UI, 323.1 million – 393.5 million).

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trend analysis and pdf report creating capabilities. The MicroLab and MicroLoop are battery operated and shipped complete in a hard plastic carrying case. For full details on these devices, contact Ann Therriault 1-800-588-3381 x1012 or visit our website www.mdspiro.com.

Monitored Therapeutics Goes Wireless

Monitored Therapeutics' latest news is the release of the GoSpiro with Bluetooth Low Energy wireless radio, enabling use with both iOS and Android based data collection platforms. As the first spirometer specifically designed for connected health applications, it provides diagnostic quality test results, delivering reimbursable spirometry data and making the results acceptable for clinical trials conducted at home. It is one of the few home spirometers that can measure FVC and flow below 0.025 L/sec. Besides its real-time flow and volume streaming data for on-screen visualization with full FV-loops and both inspiratory and expiratory data analysis, it's the only spirometer cleared for home use that has an automated Slow Vital Capacity program with all lung subdivision measurement capability. Its unique vertical turbine produces volumetric based measurements directly at BTPS that meet all ATS/ERS/ISO waveform requirements and provides for long-term calibration stability as well as avoids the need for temperature and humidity correction. It is the only FDA cleared spirometer that meets the new stringent ISO and FDA Home-Use standards. The built-in quality control parameters with calculated error indices and the available "Lisa" avatar with real-time patient coaching and test review assure lab-quality results from patients who are self-testing at home.

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VENTILATION ROUNDTABLE

Hayek Medical Devices

What ventilation products does your company offer?

Hayek Medical is the exclusive provider of Biphasic Cuirass Ventilation (BCV) therapy.

Hayek Medical's product offerings include:

- **United Hayek RTX biphasic cuirass ventilator.** This is a device designed for acute and long-term noninvasive ventilation that doesn't require a facial or invasive interface like other

forms of vent support. In certain cases extubation or tracheal decannulation can be expedited with the use of BCV. The RTX can also provide an adjunct to conventional positive pressure ventilation that frequently improves gas exchange over PPV alone. The RTX also functions as a lung recruitment tool using negative pressure to open areas of atelectasis the way nature intended with negative lung inflation pressure. Unlike any other ventilator, the RTX delivers positive extrathoracic pressure to assist with exhalation allowing control of both phases of the respiratory cycle, not just inhalation. Another feature the RTX offers is a means of built in airway clearance with high frequency chest wall oscillation and assist of cough.

- **United Hayek SCS.** This is our newest product designed for airway clearance use via cuirass interface. As with the RTS the SCS uses an oscillation wave that is both positive and negative to generate very intense intrathoracic pressure and flow effects for thinning and mobilization. Applied with the custom fitted foam sealed cuirass the SCS will provide the most comfortable yet intense HFCWO possible. Uniquely capable of supported assistance of increased cough flows with an assisted cough mode following oscillation in cycle for therapy that provides thinning, mobilization as well as support of expectoration of retained pulmonary secretions all with the amazing comfort of a cuirass interface.

Tell us about your company's current or recent R&D efforts.

United Hayek's technology for moving air, currently, in and out of a cuirass is phenomenal, needing to be seen and felt to be believed. The development and future application of

this capability means United Hayek will be a very important part of the future of the pulmonary support market. In the immediate future for us is our Secretion Clearance System device, the SCS. All of the very potent high frequency chest wall oscillation and assist cough functions that the RTX can apply through the cuirass will be available at a much lower cost profile for patients needing only the airway clearance functions. Hayek Medical is involved in multiple research activities internationally that are further validating BCV as a means to improve clinical outcomes.

Discuss the training and support services you offer.

BCV, even though it is a far more natural way to support patients is for most clinicians a totally new set of concepts. All of the adjustment criteria and side effects of ventilation historically taught for so long are turned upside down with BCV and no longer apply. This is a method of support that is actually therapeutic to the lungs and other systems. Additionally due to our similarity to previous generation of negative pressure ventilation (NPV) devices any clinicians erroneously feel they know our devices' capabilities. The Hayek so greatly exceeds the capabilities of those devices from the past, it is astonishing to those experienced with the old NPV systems. The patient's this therapy can serve are not limited to those with basic support needs. This means we need to educate caregivers on the concepts of this new type of support and how it works differently. We routinely provide full staff training on initial installation with follow up all the way to advanced training as users gain experience with the interventions available with BCV. As to support, we have clinical specialists that are available to our users

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on site as needed and through our company support line at any time. We also have a BCV discussion group on LinkedIn where users can discuss and relate their experiences with these devices.

Where are your products used?

The United Hayek ventilators and secretion clearance products are used across the spectrum of care. If applied in the ER, an ICU or even hospital admission may be prevented even when other forms of NIV fail. If used as part of ICU care, support can be non-invasive. This means fluid intake, nutrition and communication with the patient are not impaired and duration of critical care needs can be decreased. One of the most challenging and perhaps expensive patients hospitals deal with are the patients that move out of ICU, decompensate for lack of pulmonary support some time later and have to return to ICU more critical than when they were when originally admitted. If these patients are moved to the floor or step down unit with the Hayek, they will be more likely to achieve discharge on schedule. Since the Hayek can be prescribed for patients of all age groups at home and is much simpler to use with less side effects than either invasive positive pressure ventilation (PPV) with trach or non-invasive PPV with mask and it includes airway clearance functions built in to the vent, patients that discharge with this device may return to acute care in the future, but the potential of their return being for reasons of pulmonary exacerbations is greatly decreased thus preventing frequent readmissions for these causes. As well the SCS has applications for airway clearance with cough assist in all settings. So as you see Hayek covers the entire spectrum resulting in improving the patient's experience and saving money by decreasing intensity and duration of intensive care and also allowing care with these therapies to continue in the long term.

What developments do you foresee for ventilation products and applications?

We have made great strides as an industry in meeting the pulmonary support needs of our patients and we have seen advances in technology toward the end of protecting the lungs and enhancing patient/ventilator synchrony that I believe make real difference in patient comfort and outcomes. I foresee one major shift that can have a profound effect on future outcomes for patients needing support in the future. As people realize what Hayek Medical Devices has to offer with these products they will include this therapy more and more in standard treatment protocols to improve results. The RTX can be used as a totally stand alone non-invasive support device that provides the advantages of far more natural support of lung inflation and deflation without mask or artificial airway, which is far more comfortable for most patients and preserves their ability to eat, drink and speak, which is often not the case with alternatives. BCV can also be used non-invasively in conjunction with PPV to dramatically decrease side effects and improve on clinical results. The use of BCV to facilitate weaning from PPV, shorten duration of intubation, and potentially prevent need for trach is another advancement that is on the increase. Most respiratory practitioners are aware that natural ventilation with negative pressure lung inflation is always better than PPV but until Hayek came on the scene we did not have a good way to provide that type of support. Now with these devices from Hayek there is a good way. It all becomes clear when BCV is placed on a patient in respiratory distress.

Hamilton Medical

What ventilation products does your company offer?

Mechanical ventilators, humidifiers, and cuff pressure controllers. These products include:

- **HAMILTON-G5:** Hamilton Medical's most modular high-end mechanical ventilator. A large set of standard features and options allow you to tailor the HAMILTON-G5 to your needs. The unique integrated cuff pressure controller IntelliCuff continuously monitors and automatically adjusts cuffed tracheal and tracheostomy tubes, providing real-time optimization of cuff pressure.
- **HAMILTON-C3:** A compact high-end ventilation solution for all patient groups. The compact design and independence from external power and air supplies allow for maximum mobility throughout the hospital. The integrated high-performance blower guarantees optimal performance even with noninvasive ventilation.
- **HAMILTON-C2:** A universal ventilation solution for all patient groups. The HAMILTON-C2's compact design and independence from external power and air supplies allow for maximum mobility throughout the hospital. The integrated high-performance turbine guarantees optimal performance even with noninvasive ventilation.
- **HAMILTON-C1:** Combines invasive and noninvasive modes with maximum mobility. This makes it an ideal companion for all patient groups in the intensive care unit, emergency ward, recovery room or intermediate care, long-term acute care facilities, and during intrahospital transport.
- **HAMILTON-C1 neo:** A versatile neonatal ventilator that combines invasive and noninvasive modes with the additional option of nCPAP. The integrated turbine allows it to be operated independently of a compressed air supply. Due to its compact design, it is an ideal companion for your smallest patients in various environments such as delivery room, the intensive care unit and emergency ward, as well as during intrahospital transport.
- **HAMILTON-T1:** Combines for the first time the functionality of a fully featured intensive care unit ventilator with the compactness and ruggedness required for transport. This is why the HAMILTON-T1 enables you to provide optimal ventilation therapy to all patient groups during transport, from the neonate to the adult.
- **HAMILTON-MR1:** The fully featured ICU ventilator guarantees uncompromised continuous ventilation care from the ICU to the MRI scanner and back. Its reliability and high performance, with advanced lung-protective strategies and patient-adaptive modes, make the HAMILTON-MR1 the ideal choice for any critical care department that needs to transport ventilated patients to the MRI department.
- **HAMILTON-H900:** The HAMILTON-H900 humidifier has been developed with focus on ease of use and patient safety allowing caregivers to focus on the important aspects of patient care. It offers an innovative two-step set up to get you started quickly. All connections on a humidifier are in a single breathing set enabling one-hand operation. Due to the ergonomic design, the user interface provides all needed information at a glance.
- **IntelliCuff Pressure Controller:** Continuously optimized and controlled cuff pressure supports ventilation therapy

and secures airway management — whether you use IntelliCuff during air transport with quickly changing ambient pressure, or in the operating room for N2O narcosis or laparoscopic abdominal surgery.

Discuss the training and support services you offer.

Hamilton Medical College — this e-learning platform offers online education on mechanical ventilation, FREE and OPEN to everyone. For some modules, a certificate is issued upon successful completion. In addition, for the successful completion of some modules you will receive Continuing Respiratory Care Education (CRCE) credits from the American Association of Respiratory Care (AARC)

Hamilton Medical offers Service Training courses for the Hamilton Medical critical care line of ventilators. Service training for the HAMILTON-C1, HAMILTON-T1, HAMILTON-MR1, HAMILTON-C2, HAMILTON-C3, and HAMILTON-G5 ventilation systems are held at Hamilton Medical, 645 Edison Way, Reno, NV 89502 and 24 hour hotline clinical support available at 800-426-6331.

Where are your products used?

Our products are used in hospitals.

Bunnell Inc.

What ventilation products does your company offer?

For over 30 years, Bunnell has provided high-frequency ventilation products. Development of LifePulse High Frequency Jet Ventilator (HFJV) began in 1980, and in 1988 the LifePulse HFJV became the first high frequency ventilator approved for clinical use in the US. Bunnell received FDA approval and began production of the upgraded Model 204 LifePulse HFJV and 314 WhisperJet Patient Box in September of 2017. Bunnell will continue to provide rentals and support for the Model 203 LifePulse and 312 Patient Box at this time. Disposables include the Patient Breathing Circuit and LifePort Endotracheal Tube Adapters in various sizes. These can be used with either model LifePulse HFJV.

What are the new features?

The Model 204 is the New Generation of High Frequency Jet Ventilation. New features and benefits include:

- 45% smaller and lighter than LifePulse 203, with optional pole stand cart for increased mobility and a smaller footprint at the bedside
- Prioritized Alarm System
- Built-in Battery Backup
- Oxygen Analyzing Port

Tell us about your company's current or recent R&D efforts.

Bunnell's R&D department was pivotal to FDA approval for the Model 204 LifePulse HFJV and 314 Patient Box. They played a vital role in the FDA approval for an additional size 3.0mm LifePort Endotracheal Tube adapter, which was released to market in 2017.

Discuss the training and support services you offer.

Bunnell is committed to continued education and support for the LifePulse, which is always free of charge. The Bunnell Hotline is available to clinicians 24/7/365 at 800-800-4358.

Where are your products used?

The LifePulse HFJV is used in Level III and above Neonatal Intensive Care Units.

What developments do you foresee for ventilation products and applications?

Bunnell continues to improve current products and develop new devices that serve the company mission statement — “We Save Babies.” Bunnell is 100% employee-owned and operated.

ResMed

What ventilation products does your company offer?

ResMed offers the world's first cellular cloud-connected in-home life-support ventilators: Astral 100 and Astral 150. Both are lightweight, portable and easy to use, while providing up to eight hours of internal battery life. Astral is used for a range of respiratory conditions, including chronic obstructive pulmonary disease (COPD), restrictive thoracic disorder and neuromuscular diseases (NMD), as well as for some pediatric disorders.

What are the new features?

Astral's latest features are:

- **Cloud-connected remote patient monitoring** via ResMed's secure AirView network, which shares patients' usage data with their physicians and home medical equipment providers. AirView is the world's largest remote monitoring platform, with more than six million respiratory care and sleep apnea patients registered.
- **Pressure Support with Safety Tidal Volume (PS/SVt)** is Astral's newest algorithm that targets tidal volume, providing patients with a volume guarantee, along with the flexibility of using a standard leak circuit and vented mask. The mode was previously available in a valve circuit, but has been extended for use with a leak circuit.

Tell us about your company's current or recent R&D efforts.

At ResMed, we continually dedicate 7% of our revenue toward R&D and support research that has practice-changing potential. For example, ResMed supported a trial known as HOT-HMV, published in May 2017 in the peer-reviewed Journal of the American Medical Association (JAMA). It showed that home non-invasive ventilation (NIV) therapy may significantly reduce the risk of re-hospitalization and death in patients with COPD. Those who received home NIV in addition to oxygen therapy had a 51% decreased risk in re-hospitalization or death compared to those who received oxygen therapy alone [HR=0.49, 95% CI=(0.31, 0.77) p=0.002].

Discuss the training and support services you offer.

ResMed offers its partners in-person, webinar and digital training via the ResMed Academy Online at no cost. The Academy offers online courses for continuing education credits (CEUs) as well as non-credit courses and product tutorials. Through the ResMed Academy Online, users can learn more about ResMed products, how to create workflow efficiencies and ways to improve patient outcomes.

We've released a new CEU course related to the care of respiratory patients:

- **COPD Overview: From Diagnosis to Home Ventilation.** This CEU was created to educate sleep technicians and

respiratory therapists on how to diagnosis, manage, and show the benefits of using home mechanical ventilation (eg NIV). This course is approved by the AARC, the BRPT and the CABRN for 1 credit. Duration: 60 minutes.

Where are your products used?

ResMed's ventilation and sleep devices are designed for easy use in the home, hospital and on the go. Astral patients can experience greater mobility, knowing they have eight hours of back-up power in a seven-pound device. Daytime activities can be scheduled with confidence. Astral is also a great device for intra-facility transports. Its size and weight allow it to be used during transfer and mobilization of patients in sub-acute areas, and to promote the pulmonary rehabilitation process.

What developments do you foresee for ventilation products and applications?

Remote patient monitoring continues to expand in respiratory care, sleep, cardiovascular, endocrine and other disease segments. More than seven million patients worldwide were remotely monitored via a medical device by the end of 2016, a 45 percent increase from 2015, according to tech analyst firm Berg Insight. For healthcare systems to reach their greatest potential, their care networks need to connect to one another. Connectivity not only increases workflow efficiencies, but also offers tools to provide better patient care. We are seeing an increasing number of manufacturers working on ventilation data capabilities. Developments are focused on EMR integrations, cloud-based patient management applications, solutions to manage patients by exception, and automated patient coaching tools. These capabilities will likely become standard of care for ventilation devices.

imtmedical

What ventilation products does your company offer?

imtmedical ag sells the universal bellavista 1000 ventilator in the US. This has both invasive and non-invasive ventilation modes and impresses with unsurpassed performance in terms of quality and safety of the ventilation. We also offer three additional ventilators worldwide: the bellavista neo for the gentle and extremely precise ventilation of neonates and infants, the bellavista mr for unrestricted ventilation in an MRI environment and the bellavista 1000e with a large screen for even better clarity. In addition, imtmedical Pte. Ltd. offers flow sensors for working with ventilators. iFlow sensors are available in different versions, for single or multiple use in neonatal ventilation through to the ventilation of adults. They provide maximum precision in the pressure and flow delivered, and also meet the highest safety standards thanks to the robust design.

What are the new features?

Synchronisation tools, gentle invasive ventilation modes and various non-invasive ventilation modes are particularly topical. Our auto.sync synchronisation tool, for example, frees patients from fixed expiratory trigger settings and optimizes synchronisation during spontaneous breathing; auto.leak, on the other hand, compensates leaks up to 120 L/min during inspiration and expiration and therefore significantly increases the safety and quality of the ventilation. Users of our ventilators can also get an overview of their patients' breathing much easier and quicker with our new AnimatedLung. This graphical tool

shows at a glance the lung compliance, lung resistance and spontaneous breathing of a ventilated patient.

Tell us about your company's current or recent R&D efforts.

We continue to pursue developments with our advisory board, a committee of internationally renowned ventilation experts, in order to be able to offer our customers the best ventilators. For example, this concerns new ventilation modes and forms of therapy, but also synchronisation tools — they can be used to significantly reduce the users' workload, but also to increase the quality of the ventilation at the same time. In addition, it is very important to us to be able to incorporate current technological advances in the development of our ventilators. This enables bellavista's performance to be gradually enhanced.

Discuss the training and support services you offer.

imtmedical supports users of its ventilators and measuring devices in a number of ways. For example, we run webinars on a regular basis where we demonstrate the different features and possible applications of our devices — the participants have the opportunity to ask questions, which is very important to us, so that they really get any answers that they need. The webinars are then available as a video and can be used to learn about the features of our devices through self-tuition. In addition, our ventilation and measurement specialists run training courses on the operation and maintenance of our devices all over the world. Our well-established network of globally active employees and business partners also ensures that we can provide optimum support to our customers wherever they are — this kind of service is something quite normal for us. Our support and training activities are rounded off with a variety of flyers, brochures and manuals to allow users to learn about our ventilators and their performance and to use them in the best possible way.

Where are your products used?

Bellavista ventilators are primarily used in intensive care medicine, for example during or after surgery. In addition to our universal bellavista 1000 that is approved in the USA, imtmedical offers additional ventilators worldwide: the bellavista neo and the bellavista mr — the first one is specifically for use in neonatal departments and the second one is for ventilation during MRI scans.

What developments do you foresee for ventilation products and applications?

A very topical issue is the networking of medical devices over the internet — so-called cloud computing. This is already technically feasible but it has failed so far on organisational issues, particularly in hospitals. Networking should be straightforward from the user's point of view because they are familiar with Bluetooth and Wi-Fi from their mobile devices. IT departments view this more critically because they have security concerns in this respect due to data loss or unauthorised access. With the ongoing development of the technical possibilities, this topic will definitely still be given a lot of our attention in the future and become reality everywhere in just a few years. In addition, we expect that the number of synchronisation tools and smart ventilation modes on ventilators will increase in the future. We are in the process of refining our existing ventilation modes and creating new ventilation modes and forms of therapy in cooperation with our advisory board.

ZOLL Medical

What ventilation products does your company offer?

ZOLL offers easy to use, portable transport ventilators. We have three products to meet the needs of multiple markets: inter-hospital and intra-hospital transport, the MRI suite, critical care transport, EMS, and the military. All of our products have SmartHelp™ technology to help guide users through alarm resolution. And with our built-in compressor design, ZOLL ventilators consume less oxygen (Study: Assessment of oxygen consumption from standard E cylinders by fluidic, turbine, and compressor style portable mechanical ventilators, University of Cincinnati) than many other ventilators available on the market.

What are the new features?

New in 2017, ZOLL ventilators include inverse I:E ratio as well as plateau pressure (P_{PLAT}) measurement, allowing clinicians to provide more tailored patient care for high-acuity patients such as acute respiratory distress syndrome (ARDS).

Tell us about your company's current or recent R&D efforts.

In addition to driving technology advancements in all of our products, ZOLL's product development efforts focus on device integration. As ZOLL offers a breadth of products across acute care, we continuously strive to deliver technologies that cover the spectrum of our customers and their patients' multiple needs, including a focus on ventilation therapy.

Discuss the training and support services you offer.

ZOLL has a dedicated training team that is comprised of clinicians. We offer training that allows our customers to have a clinician-to-clinician experience when working with our products. Additionally, we offer technical support from our corporate headquarters near Boston, Mass., as well as at the customer site.

Where are your products used?

ZOLL ventilators are used in many places where portable ventilators are used, both in and out of hospital. ZOLL ventilators are ideal for patient transport, because they weigh less than 10 pounds, have a 10-hour battery runtime, and consume less oxygen than many other ventilators on the market. In addition, ZOLL ventilators are MRI conditional, supporting users to provide more controlled ventilation in the MRI suite.

What developments do you foresee for ventilation products and applications?

In addition to our enhanced features and modes, we foresee that ventilator products will continue to improve on smart alarm systems to help reduce alarm fatigue. While ZOLL ventilators currently offer SmartHelp technology to help guide users through alarm resolution, we are excited that other companies in the market are striving to achieve the same goal.

New Advancements in Blood Gas Analyzers

In this feature, Respiratory Therapy interviews clinicians and healthcare providers about the actual application of specific products and therapies. In this interview, we speak with John Ancy, MA, RRT of Instrumentation Laboratory.

Respiratory Therapy: Instrumentation Laboratory received FDA clearance for a new blood gas analyzer. What advancements does the new model offer?

John Ancy: The GEM® Premier™ 5000 system with Intelligent Quality Management 2 (iQM®2) was built upon the knowledge gained from development and production of the GEM Premier Family of blood gas analyzers with iQM. New iQM2 automates quality assurance with continuous cycle of five quality checks — before, during and after every sample for a complete picture of quality.

Additionally, as with all GEM Premier analyzers, the GEM Premier 5000, uses a single GEM PAK cartridge containing all required analytical components; however, with the GEM Premier 5000, onboard use-life of the GEM PAK has been extended to 31 days*. Other new features of the GEM Premier 5000 include: customizable quick-start user interface with smart-color status bar, illuminated universal sampler, Auto PAK Validation and 45-second time-to-result, enhancing efficiency and work flow.

RT: Can you describe key aspects of the quality management offered by iQM and iQM2?

JA: iQM/iQM2 are statistically based process-control systems with well-defined performance maximizing probability of error detection, minimizing time to error detection and the probability of false rejection. iQM/iQM2 provide continuous, real-time monitoring of all analyzer components and processes that could affect result accuracy. iQM/iQM2 monitor sensors for drift or slope changes that could affect result accuracy and automatically adjusts sensor output when required, use pattern recognition to identify common errors, including micro-clots and interferences (e.g., thiopental, benzalkonium) and initiate automatic corrective actions and documentation. iQM2 features IntraSpect, a major advancement in quality assurance, which detects abnormal sensor response or residual error during the measurement process.

RT: How does IntraSpect work and how does that improve quality?

JA: IntraSpect collects sensor readings during the last 15 seconds of sample analysis, enabling the detection of transient errors during sample measurement that traditional external quality control cannot. Pattern Recognition software analyzes the sensor readings prior to result reporting. Abnormal sensor

responses are identified through slope shape and coefficients outside acceptable limits are suppressed and flagged, greatly reducing the potential for erroneous results reporting. No other blood gas analyzer offers this level of quality management and assurance. iQM2 with IntraSpect provides continuous monitoring of the analytical process before, during and after each sample measurement.

RT: Are there any clinical studies on IntraSpect?

JA: Field data collected over six months on 280,000 samples demonstrates 0.6% error detection rates or approximately one transient error per 167 samples with IntraSpect. These transient, sample-specific errors were likely caused by micro-clots, micro-bubbles, fibrin or interfering substances, and if not detected, may have caused erroneous results.

RT: What is Auto PAK Validation?

JA: Auto PAK Validation (APV) is an automated calibration-validation process in the GEM Premier 5000 system. APV utilizes onboard, Process Control Solutions, included in the GEM PAK, with known concentrations of all analytes. APV is automatically analyzed following insertion and warm-up of a new PAK and before patient sample testing is permitted. The operator simply installs the PAK, ready approximately 45 minutes after installation.

RT: In today's demanding healthcare, how can the GEM Premier 5000 system with iQM2 be used to improve patient care?

JA: GEM Premier analyzers are designed to automate all key labor-and skill-intensive tasks, including: quality management, system maintenance, and information management with GEMweb® Plus Custom Connectivity. The GEM Premier 5000 system with iQM2 further streamlines operation, decreases sample analysis time, and assures sample quality before, during and after sampling. This combination of advanced simplicity and enhanced quality makes the GEM Premier 5000 system with iQM2 ideal for point-of-care testing. Most importantly, Respiratory Therapists can focus on patient care, rather than on an analyzer, and be assured quality results.

*21-day onboard use-life for 600-test PAK.

If you would like to participate in this feature, as a company or healthcare provider, please contact Steve Goldstein at s.gold4@verizon.net.



The Intelligent Analyzer.

Assuring quality before, during and after sample analysis—for improved patient care.

New GEM Premier 5000 Critical Care whole-blood* testing system provides automated quality assurance with every sample. Now with next-generation Intelligent Quality Management (iQM2), featuring *new* IntraSpect™ technology, potential errors are detected not only before and after, but also *during* sample analysis, along with real-time correction and documentation. Plus, it's simple—just change the all-in-one GEM PAK once a month. So regardless of testing location or point-of-care operator, quality results and compliance are assured with every sample.

Real-time assurance and advanced simplicity. Now that's intelligent.

For more information in North America, call 1.800.955.9525 or visit instrumentationlaboratory.com

Outside North America, visit werfen.com

*Heparinized.



Not available in all countries.

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The Benefits of Remote Monitoring on CPAP Patient Management

In this feature, Respiratory Therapy interviews clinicians and healthcare providers about the actual application of specific products and therapies. This interview is with Greg Schoonover, President of Health Technology Resources, about the company's Solutions for Sleep.

Respiratory Therapy: What was CPAP patient management like before remote monitoring?

Greg Schoonover: It used single server data that was time consuming, labor intensive and many times unreliable. What we mean by unreliable ranges from corrupt data cards, patient's failure to send in data cards or re-insert their cards properly and data cards lost in the mail.

RT: What issues did this cause for clinicians and patients?

GS: Unreliable and inconsistent data made it difficult to verify compliance and receive reimbursement for care provided. It also made it hard to provide many patients with optimal care, since we rely on good data to flag when a patient could benefit from specific usage coaching or a therapy setting change to achieve better health outcomes.

RT: What specific remote monitoring solutions do you use?

GS: We use AirView (the world's largest remote patient monitoring network with more than 6 million patients), U-Sleep and Encore Anywhere.

RT: How much has HTR increased its overall CPAP patient adherence since implementing these solutions?

GS: Our remote monitoring has been ongoing since 2010. Over the course of these years we have taken our compliance rate from a 60% range to 80% due to improvements in technology and our ability to manage the data. We acquired our patient compliance outcome data directly from ResMed. Because of software like this, we can make internal process improvements that result in HTR achieving patient compliance in 4 out of 5 patients we serve. That is very rewarding for us as well as our patient population.

RT: Are patients engaging in connected health solutions as well, such as through an app to track their therapy?

GS: We feel a good number of our patients are engaging in connected health through the capability of using their app, such as ResMed's myAir app, which 1,300 new patients sign up for every day. Understanding and implementing their app is part of our educational process at set up where many patients download the app at that time.

RT: What features within these solutions do HTR find most effective for improving patient outcomes?

GS: a. The ability to manage patient data by exception and next day patient contact when required.
b. Having the capability of real time patient monitoring.
c. Having remote diagnostics of equipment.

RT: What features have a significant impact on HTR's business efficiencies?

GS: Data analytic tools and competent staff will have the most significant impact on business efficiencies. Specifically, cloud based data collection, real time patient monitoring, equipment diagnostics and development of your patient management and intervention through developed rule sets.

RT: Do you think connected health is the latest trend or a mainstay in respiratory therapy?

GS: The ability to quickly manage a patient's adherence to therapy, provide efficacy data to the medical care team including payers as well as better management of ongoing patient and supply needs put connected health into the mainstay category of respiratory therapy.

RT: What additional services do you hope connected care solutions can provide in the future?

GS: We are seeing lots of patient monitoring apps being developed for the health care professional as well as the consumer. We are excited to discover which ones we will be able to integrate into our programs that give us and the health care team an even broader picture of patient status.

RT: Anything else you'd like to add?

GS: Data continues to be king. Those who are able to derive meaningful practice insights backed by reliable data and patient exchange will stand out as the leaders in the DME industry. As a business executive, it is my job to see how technology can provide information that allows our team to solve patient compliance issues within 24 hours of identifying the patient's problems or issues. It allows our staff to interface with the patient on fact based data which can quickly lead to patient problem resolution and faster compliance. Faster compliance makes happier patients.

If you would like to participate in this feature, as a company or healthcare provider, please contact Steve Goldstein at s.gold4@verizon.net.



Revolutionizing the patient-provider relationship through connected health

As the largest provider of connected health solutions for remote monitoring*, ResMed leads the way in helping patients, providers and physicians communicate and share data. Harnessing the power of digital health devices and cloud-based software, ResMed is transforming how the respiratory care industry diagnoses, treats and manages chronic diseases while decreasing health system costs. Through this connected ecosystem, providers have the tools to maximize patient therapy adherence and manage patient populations more effectively.

Learn more about ResMed connected health at ResMed.com/AirView



*Berg Insight: 2017 mHealth and Home Monitoring report

The Benefits of Sil.Flex TC Pads for Prevention of Stomal Erosion

In this feature, Respiratory Therapy interviews clinicians and healthcare providers about the actual application of specific products and therapies. This interview is with Carol Montiel RN, MS, Director of Golden Glades United Community Options of Miami, formally United Cerebral Palsy.

Respiratory Therapy: Tell us about your facility and clients.

Carol Montiel: Golden Glades is a Special Medical home for children and young adults with Cerebral Palsy and other diseases. The home is licensed by APD and located in Miami, Florida. The house, formally known as Baby House, supports 15 permanent clients that reside at the home 24 hours/7 days per week. There are a total of 12 clients with tracheostomies; 9 patients using ventilators and the remaining clients have other issues. They are medically fragile, non-ambulatory and physically and developmentally disabled.

RT: How did you find out about the Sil.Flex TC Pad for your patients?

CM: Dr Antonio Rodriguez, Director of Pediatric Pulmonology at Nicklaus Children's Hospital in Miami, Florida, presented the Sil.Flex™ TC Pad to me. He discussed the Sil.Flex TC Pad as potential solution for prevention of stomal erosion due to movement of the circuit and tracheostomy tube and stomal leaks for ventilated clients. Art Rodriguez, RRT with Sovereign Medical had recently presented the benefits of the Sil.Flex products to him.

RT: What clinical benefits have you found with use of the Sil.Flex TC Pads with your clients?

CM: After discussing the clinical benefits we applied the Sil.Flex TC Pad to several clients; one in particular. I had been looking for an answer to a problem with this client who was constantly growing granulomas in and around the stoma site. The granulomas had to be removed surgically. This particular client moves his head back and forth causing stomal irritation and the added weight of the ventilator circuit had exacerbated the condition making it even worse. I had researched with colleagues and the internet for a solution to the stomal irritation and was not able to find a good resolution for this client. After a discussion with Dr Antonio Rodriguez and Art Rodriguez the Sil.Flex TC Pad was presented as a potential solution. After use of the Sil.Flex TC Pad with this client, we noticed a difference at the stomal site and the granulomas were not growing. In addition, we have started the use of the Sil.Flex TC Pads with our other ventilated/trach clients who appeared to have stomal irritation due to constant movement. The Sil.Flex TC Pads have alleviated the tugging of the ventilator circuit and we have noticed clients are more comfortable.

RT: How does the Sil.Flex TC pad assist clinicians in better client outcomes?

CM: In our experience we have found better outcomes with the Sil.Flex TC Pad and this has translated into less transport of our ventilator clients to ENT surgeons and more importantly it has minimized surgical intervention for removal of granulomas. In addition, we have noticed less stomal leak and improved ventilation in our clients.

RT: What recommendations would you make to other facilities?

CM: For facilities that have ventilator clients, I highly recommend using the Sil.Flex TC Pad because it alleviates the tugging of the ventilator circuit around the stoma site every time the client moves their head back and forth.

RT: What improvements have you found with use of the Sil.Flex TC Pad?

CM: The best improvement is that our clients are more comfortable and tolerant of the trach, we see improvement of their skin, less stomal redness/irritation and no growth of granulomas. We have found the Sil.Flex TC Pad provides a more stable positioning of the trach device in the stoma site, clients tolerate the trach better and it is easier to clean and maintain the trach site. We are pleased to have found a good solution for our trach clients and recommend the use of the Sil.Flex TC Pads for trach clients.

If you would like to participate in this feature, as a company or healthcare provider, please contact Steve Goldstein at s.gold4@verizon.net.

2 is Not 2 is Not 2

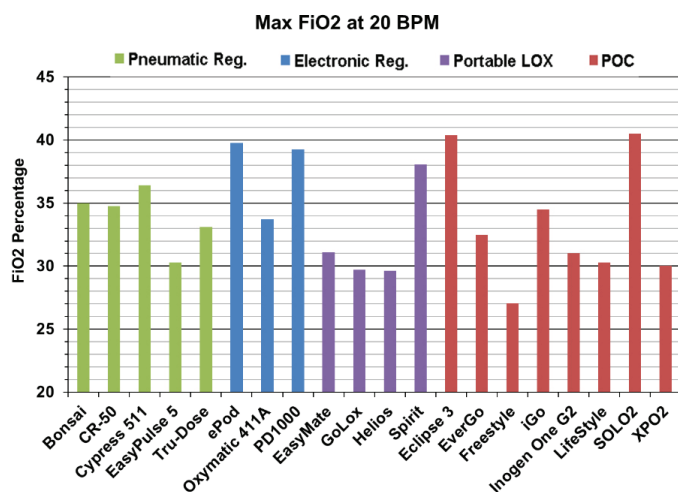
The fundamental flaw in perception when providing long-term oxygen therapy (LTOT) to a patient

Brian W Carlin, MD, FCCP, FAARC, Robert McCoy, BS, RRT, FAARC, Ryan Diesem, BA

The Reality – 2 liters per minute continuous flow is not equal to a 2 setting on an intermittent flow (IF) device. A 2 setting on one intermittent flow device is not equal to a 2 setting on a different intermittent flow device. Therefore, for oxygen delivery devices: **2 is not 2 is not 2¹**.

Fundamentals of oxygen therapy

Oxygen is the fuel that drives life. Every cell requires the proper amount of oxygen to function properly and without proper oxygen levels, complications occur.²



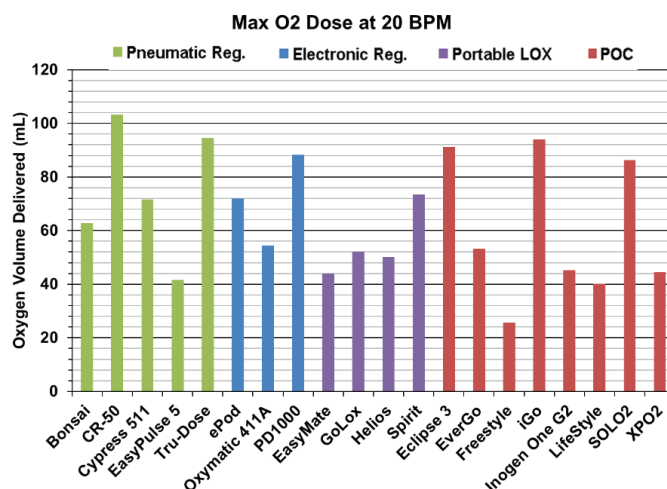
The maximum FiO2 of a variety of portable oxygen systems, utilizing intermittent flow at 20 breaths/min varies greatly.*

The maximum oxygen dose of portable oxygen systems, utilizing intermittent flow at 20 breaths/min varies greatly.*

*Although research exists, more research is needed to explore recent product improvements and new additions to the market.

Normal oxygenation occurs naturally in a healthy body with healthy lungs, yet when lung disease compromises lung function, hypoxemia occurs. Supplemental oxygen therapy is provided to maintain normal oxygen level, yet can only be effective if given in adequate doses to sustain effective oxygenation. When

Dr Carlin practices pulmonary, critical care, and sleep medicine in western Pennsylvania. He is active within several national organizations including the American Association of Cardiovascular and Pulmonary Rehabilitation, CHEST, and the American Thoracic Society. He is the current chair of the National Lung Health Education Program and is a member of the National Board for Respiratory Care. Robert McCoy is the Managing Director of Valley Inspired Products Inc. Ryan Diesem is the Research Manager of Valley Inspired Products Inc.



providing supplemental oxygen, it cannot be assumed that the oxygen device will provide adequate oxygenation due in part the variability of the devices, oxygenation must be measured at all patient activity levels due to the variability in performance of different oxygen therapy equipment.³

Oxygen is a drug that needs to be prescribed, delivered and monitored like any other drug.

Oxygen is the only drug that has been shown to maintain and prolong life of patients with chronic lung impairment.

Reference: Continuous or nocturnal oxygen therapy in hypoxemic chronic obstructive pulmonary disease: a clinical trial. Nocturnal Oxygen Therapy Trial Group. Ann Intern Med 1980;93(3):391-398.

Hypoxemia and comorbidities

Cor pulmonale

When oxygen is not provided at therapeutic levels, the body will compensate. The pulmonary vasculature will divert blood flow to areas of the lung that have effective oxygen levels. If this is not possible, pulmonary blood vessels will constrict causing blood to back up into the heart and peripheries of the body.

Polycythemia

The blood will compensate by producing more hemoglobin to increase the oxygen carrying capacity of the blood. This thickening of the blood impacts circulation.

General cellular dysfunction

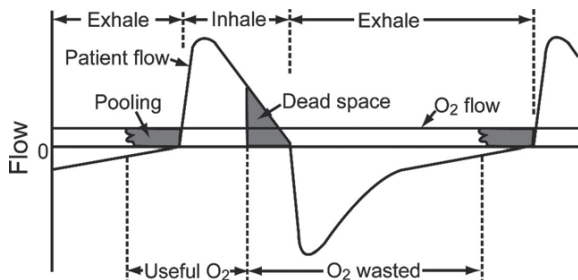
All other organs in the body will slow their function in the response to low oxygen levels.⁴

Basically, the body does not function well without therapeutic oxygen levels, which begins a downward progression of body mechanics to the point where patients will reduce activity, retain secretions and eventually develop chest infections requiring medical intervention. These occurrences are the exacerbations that occur with oxygen-deprived patient and cause them to become the frequent flyers that cost healthcare systems penalties under the ACA.

History of the evolution of continuous flow oxygen therapy to intermittent flow oxygen delivery

Continuous flow (CF) oxygen was the original method of oxygen therapy due to the simplicity of delivery and limitation of technology. The limitation is CF wastes oxygen by delivery flow when the patient is exhaling and pausing between breaths. The fixed flow also allows for FiO₂ to drop when respiratory rate increases shortening inspiratory time.

VIP graph of flow delivery reference 2013 article



Above: Diagram of a respiratory flow cycle in relationship to continuous-flow supplemental oxygen, indicating the sections of the breathing pattern that useful oxygen is delivered.

Continuous flow, oxygen conserving options:

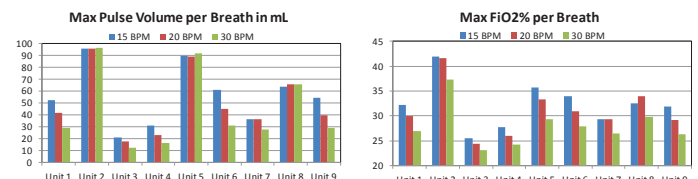
- Transtracheal oxygen – a method of bypassing the upper airway and reduces dead space which allows improved use of oxygen and improves patient compliance due to elimination of cannula irritation.
- Reservoir oxygen systems – utilizes a 20 mL reservoir to store oxygen between breaths improving efficiency of oxygen delivery and conserves oxygen.

Intermittent oxygen delivery options (provides oxygen when the patient is inhaling and turns off with exhalation):

- Demand flow allows for oxygen delivery at the same flow rate as prescribed oxygen which is usually 2 LPM.
- Hybrid flow allows for a higher peak flow of oxygen at the beginning of a breath then returns to the flow rate prescribed.
- Pulse dose provides a higher peak flow at the beginning of a breath and cycles off when the volume of oxygen is delivered. This keeps the volume of oxygen consistent throughout a range of breath rates.
- Minute volume delivery is a fixed delivery of oxygen for one minute. If respiratory rate increases, the volume of gas delivered will decrease to maintain the fixed minute volume.

Why different intermittent flow devices are not the same at the same setting, the first step in explaining 2 is not 2 Pulse volume

Pulse volume at an appropriate dose is the key to effective oxygenation. The volume of oxygen delivered to gas exchange units in the lung (alveoli) is how effective oxygenation occurs. Intermittent flow (IF) oxygen delivery devices are highly variable in delivering consistent volumes of oxygen. Dose settings are not consistent in delivering known volumes of gas. Gas volume, gas delivery peak flow, gas delivery in the first half of inspiration and the purity of the gas all contribute to effective oxygenation. With any change in these parameters, the FiO₂ will change and impact effective oxygenation.

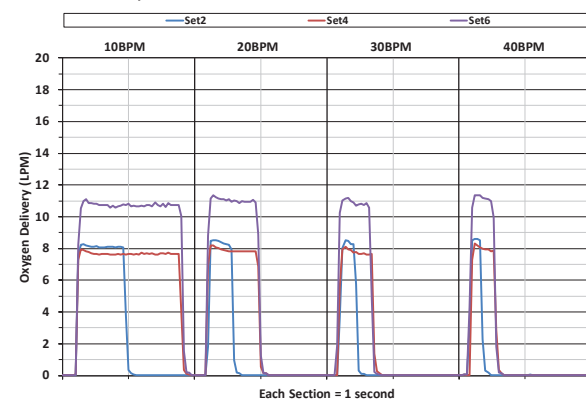


Above: Maximum pulse volumes and FiO₂ of different Pulse systems at different respiratory rates.

Inspiratory time

Inspiratory time is the window of opportunity for therapeutic gas to be delivered to gas exchange units in the lung. As a patient breathes faster, the window of opportunity becomes shorter and the gas must be delivered quickly to be therapeutic. Demand units were not effective in delivering oxygen therapeutically due to fixed/low peak flow delivery. Minute volume devices typically have a higher peak flow, which will allow gas to be delivered quickly, yet with an increased breath rate, oxygen volumes decrease with an impact on FiO₂.

Pulse Delivery Flow Profiles



Above: Flow profiles of 3 pulse dose systems showing oxygen delivery in one second. The first 60% of an inspiratory cycle is considered delivered to gas exchange units in the lung, the rest occupies dead space.

Triggering sensitivity

Triggering sensitivity is important to allow gas delivery in the early part of inspiration. The first segment of a patient's breath goes to gas exchange units in the lung; the remainder of the gas will occupy dead space and not participate in gas exchange, therefore, is wasted. If an intermittent flow device is slow to sense a patient's breath, the volume of gas that is delivered when the device does sense a breath will be delivered later in the breathing cycle and may have some of the gas occupying dead space. IF devices attempt to be as sensitive as possible, yet a nasal cannula is an open system, which causes variability in the devices ability to sense a breath. Cannula placement, tidal

volumes, inspiratory flow rates and mouth breathing are also causes for a device to be slow to trigger or miss an inspiration.

Device Variability

All intermittent flow oxygen delivery devices are different in design and function. The ability to control and deliver oxygen therapeutically depends on the capabilities of the device and the patients breathing patterns. IF system designs attempt to provide therapeutic oxygen in a device that is convenient for the patient to use.

Considerations for therapeutic oxygen delivery

- Amount of source gas available to deliver to the patient.
 - Compressed gas and liquid oxygen systems have the most available source gas on demand.
 - Portable oxygen concentrators are limited by their oxygen product capabilities in one minute (limited oxygen availability on demand).
- Dose settings with a range of oxygen volumes. The greater the dose volume, the greater the FiO₂ potential.
- Triggering sensitivity.
- Peak flow capabilities that allow for oxygen to be delivered quickly, the higher the peak flow capability the faster the oxygen can be delivered in therapeutic range.
- Consistent oxygen delivery with variable breathe rates; minute volume delivery of IF devices reduces pulse volume with faster breath rates.

Considerations for patient convenience/compliance

- Device weight – the heavier the device the less likely the patient will use the device consistently.
- Device operating time – if a device does not operate as long as a patient will be away from home, travel outside the home will be limited or the patient may not use the device consistently while away.
Issues:
 - Gas contents for a liquid oxygen or compressed oxygen cylinder.
 - Oxygen production (concentrator) battery weight, battery exchange.
- Ease of use – complicated user interface will limit a patient's use of the device.
- Esthetics – a portable oxygen system that looks like an industrial product will prevent a patient from using the device consistently in public places. Also, oxygen is perceived as a last resort option by patients which prevents some patients from using an oxygen system in public.
- Carrying options, straps, carts, etc. – if a device is difficult to incorporate into a normal use similar to purses, backpacks or other standard devices that are carried, the portable oxygen may not be utilized.

Summary

Therapeutic oxygen delivery is necessary to prevent complications, hospitalizations and increased overall healthcare cost. Oxygen is a drug that needs to be assessed correctly, prescribed effectively, delivered therapeutically and monitored consistent to insure patient benefits. Delivery options for oxygen therapy are different and need to be evaluated on a patient at all activity levels to insure effective oxygenation. A 2 setting on one oxygen delivery device is not the same as the 2 setting on another oxygen delivery device. Patient compliance with LTOT requires the combination of therapeutic oxygen delivery with a system that will allow a patient the ability to do normal activities of

daily living. To prevent complications of hypoxemia described in this paper, therapeutic oxygen delivery is the most essential component of LTOT.

Conclusion

New oxygen delivery systems are available to address the needs of LTOT patients who desire to maintain a normal lifestyle while using portable oxygen equipment. Newer home oxygen systems have become available that address the patient's lifestyle needs, yet may not provide therapeutic oxygen with all activities, therefore: Clinicians must recognize that when prescribing oxygen therapy, they must either completely understand the capabilities and limitations of the devices they will be prescribing or have a skilled clinician titrate the oxygen dose at all activity levels on the device the patient will be using.

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Cost Savings Associated with HFCWO Therapy

Gary Hansen, PhD, and Gordon Sawyer, RRT, MBA

Abstract

A large registry of patients with bronchiectasis was used to examine patient outcomes before and after initiation of High Frequency Chest Wall Oscillation (HFCWO or vest therapy).¹ This study by Barto et al (2015) found that the rate of inpatient hospitalizations dropped from 0.887 admits/patient in the year prior to beginning vest therapy to 0.404 admits/patient in the year after, a reduction of 54.5%. On average, patients avoided 0.483 hospital admits per year, with an associated expenditure reduction of \$14,039. This compares favorably to the cost of an HFCWO therapy system, which could pay for itself in less than one year.

The Benefits of Vest Therapy

HFCWO is a common airway clearance treatment for people with pulmonary disorders such as cystic fibrosis and bronchiectasis.² It consists of an inflatable vest attached to an air pulse generator that creates rapid compressions to the chest. The system's vibrations help loosen, thin and mobilize mucus so it can be expelled through coughing or suctioning. The safety and efficacy of HFCWO have been well documented in a number of peer-reviewed studies since the technology's introduction in the early 1990s. In general, HFCWO has been shown to sustain or improve the results for long-term pulmonary function tests (PFTs).³⁻⁵ Patients using HFCWO for airway clearance have experienced a lower incidence of pneumonias, hospitalizations and ICU days.⁶⁻⁸ HFCWO therapy also has been associated with reduced healthcare expenditures.^{9,10}

The Burden of Bronchiectasis-COPD Overlap

Bronchiectasis is a pulmonary disorder characterized by permanent bronchial dilatation and severe bronchial inflammation, with symptoms of chronic productive cough and recurrent infectious exacerbations.¹¹ Enlarged spaces in the bronchioles trap secretions, impairing the ability to clear secretions,¹² and leading to recurrent respiratory infections and declining pulmonary function.¹³ Repeated infections, followed by damage to the bronchial tree, comprise the main impacts of the disease.¹⁴ In the past, bronchiectasis was viewed as an orphan disease,¹⁵ however it is now known that the prevalence of this condition has been growing at a rate of 8.7% per year since 2001¹⁶ and may now be diagnosed in more than 500,000 people in the US.¹⁷

Bronchiectasis may arise from a variety of causes, but it has

long been known that a sizable proportion of cases arise from or are comorbid with COPD.¹⁸ In fact, a recent meta-analysis showed that over half of patients with moderate to very severe COPD were also diagnosed with bronchiectasis.¹⁹ The high prevalence of COPD has increased the interest in bronchiectasis, particularly because research has shown that adding bronchiectasis as a comorbidity to COPD almost doubles the risk of exacerbation or death.²⁰ It has been suggested that, rather than being coincidental, COPD and bronchiectasis comprise an "overlap syndrome" whereby both combine synergistically to produce particularly harmful outcomes.²¹

Avoiding Hospitalizations for Bronchiectasis

There is ample data showing that untreated or undertreated bronchiectasis is a risk factor for increased hospitalizations, reduced quality of life, and ultimately mortality.^{20,22} Earlier intervention may avoid worsening conditions and the need for more serious interventions at a later stage of care.²³ Nicolini et al (2013) explored the efficacy of HFCWO in patients with bronchiectasis, finding that the HFCWO group showed an increase of sputum volume, significantly reduced cough, and significant improvement in both dyspnea and quality of life measures when compared to conventional therapies.²⁴ More recent research, using a large registry of bronchiectasis patients who were also vest users, showed measurable benefits associated with the use of vest therapy.¹ The number of patients who required no respiratory-related hospitalizations increased from 50.9% in the year before vest therapy to 76.0% in the year after starting vest therapy. Conversely, the number of patients who required three or more hospitalizations dropped from 14.3% in the year prior to vest therapy to 5.6% in the year after starting vest therapy. During this time, the yearly rate of hospitalization dropped 54.5%.²⁵

Projected Savings Associated with Vest Therapy

Barto's data, along with other published sources, makes it possible to estimate the reduction in hospital expenditures associated with the initiation of vest therapy. Using Barto's paired data, the rate of inpatient hospitalizations dropped from 0.887 admits/patient in the year prior to beginning vest therapy to 0.404 admits/patient in the year after, resulting in a difference of 0.483 hospitalizations avoided per patient per year.

Utilization savings may be determined in a variety of ways, whether by using figures appropriate to a specific institution or by using published estimates. The average hospitalization charge due to a COPD exacerbation was recently reported as

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Table 1. Inpatient Hospital Admissions Before and After Initiation of HFCWO Therapy (paired data)

Before			After		
#Admits	Patients	#Hosp.	#Admits	Patients	#Hosp.
0	199	0	0	297	0
1	93	93	1	52	52
2	43	86	2	20	40
3	56	168	3	22	66
Sum	391	347	Sum	391	158
Rate 0.887			Rate 0.404		

\$29,043, based on a 4.3-day length of stay.²⁶ (Hospital “charges” refer to the cost borne by the payer and patient; hospital “costs” reflect the actual cost of patient care, which are typically lower.) Accordingly, the projected hospital charges avoided per patient in the Barto study were $0.483 \times \$29,043 = \$14,039$. When compared to the typical cost of HFCWO therapy, a one-time charge of approximately \$12,000, vest therapy pays for itself in less than one year.

This analysis has its limitations. First, the Barto study was observational and cannot ascribe causality between vest use and outcomes.

The improvement may be due, in part, to other medical interventions occurring at the same time, or to selection effects, or to regression to the mean. Second, the study used only the inCourage® System from RespirTech. Due to differences in the pulse waveform, the results may not be extendable to HFCWO products from other manufacturers. Third, the Barto study included patients with bronchiectasis who may or may not be comorbid with COPD. Therefore healthcare costs derived from COPD will only be an estimate for patients with bronchiectasis alone. Lastly, estimates of hospitalization cost vary widely and depend on the specific sample used for the calculation.

Conclusion

Use of HFCWO therapy has been associated with a reduced rate of hospitalization after initiation of use. Using a recent estimates for a COPD hospitalization, the corresponding expenditure savings are substantial and compare favorably with the one-time cost for the HFCWO device.

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The Benefits of High-performance Aerosol Delivery Devices in a Hospital Setting

Jillyan Iwinski, MBA, RRT, RCP

Case Study

A COPD exacerbation can present a challenge to the Emergency Department (ED) associated with a high risk of deterioration, the potential to require escalation of care resulting in admission to the hospital floors or ICU. The average length of stay of a COPD admission is 4-5 days resulting in average cost to the hospital ranging from \$7,242 to \$44,909.^{1,2} A high-performance vibrating mesh nebulizer can result in faster, more efficient delivery of aerosol, potentially avoiding escalation of care, reducing the risk of admission and the associated costs.^{3,4,5}

Case Summary

A 60-year-old woman presented in the ED with shortness of breath, oxygen saturation 92%, respiratory rate of 36 and an acute COPD exacerbation due to a lung infection. The patient was unresponsive to traditional small volume jet nebulizer treatments (SVN) resulting in a plan to intubate and admit the patient directly to the intensive care unit (ICU).

Prior to escalation of care and admission to ICU, the patient's aerosol delivery device was changed from a standard SVN to a high-performance vibrating mesh device (Aerogen Solo with Ultra). The patient received 2.5mg of albuterol Q2 hours with the vibrating mesh device and immediately responded as demonstrated by a SpO2 increase to 96% and respiratory rate decrease to 24, which were deemed baseline for this COPD patient. The patient verbally acknowledged feeling better and a discharge plan was initiated. Within four (4) hours the patient was discharged directly from the ED, and the escalation of care and associated costs were avoided.

Discussion

The average inpatient length of stay for a COPD exacerbations is 4-5 days.^{1,2} This patient had frequent previous admissions for COPD exacerbations and was pending intubation on arrival to the ED and inpatient admission. The patient showed improvement within 4 hours and avoided inpatient admission.

Conclusion

This patient demonstrated a rapid clinical response to treatment with a high-performance aerosol delivery device. The change from pending intubation to discharge was dramatic. It was the consensus of the team that the

de-escalation of care for this patient was attributed to the use of the vibrating mesh aerosol delivery device.

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Big Insights from Small Airwaves

Thomas F Schuessler, PhD

Oscillometry, also known as the Forced Oscillation Technique (FOT), was first published in 1956 and has for a long time been used by a select group of researchers for effortless, detailed measurements of the mechanical properties of the respiratory system. However, it is only in recent years that a wider audience is beginning to recognize its value as a technology that may produce sensitive indicators of large and small airway function during regular, quiet breathing.^{1,2,3} What has changed?

Recent Developments

For one, the equipment. Traditional FOT devices used loudspeakers to create the gentle oscillatory waves superimposed on the patient's spontaneous breathing. This resulted in bulky, stationary equipment with long "inertance tubes" and noisy fans to wash out the dead space that were, indeed, best suited for the research lab. The novel tremoflo® Airwave Oscillometry System (AOS, Figure 1) is a game-changer in this regard: using a patented vibrating mesh technology that creates the oscillatory wave right in front of the patient's mouth, the tremoflo packages a state-of-the-art Oscillometry system in a compact, handheld form factor that is by far the smallest and lightest on the market. Unlike any other FOT device, it's easy to deploy the tremoflo wherever respiratory assessment may be the most needed — not only in the PFT lab, but also at the doctor's office, clinic, hospital ward or emergency room.

New users rapidly succeed at obtaining a complete set of three valid measurements in only a few minutes, even in patients who may have difficulty performing spirometry.

Second, usability. Oscillometry has always been easy for the subject being measured: it requires only quiet breathing without a coordinated manoeuvre (Figure 2), so measurements are readily obtained in subjects ranging from 4-year-old wheezing pre-schoolers to adults with severe COPD. Unfortunately, this enormous advantage was often lost because past FOT systems required highly skilled operators to tease valid outcomes out of complex software. Here too, the easy-to-use tremoflo software breaks new ground: after brief training, new users rapidly succeed at obtaining a complete set of three valid measurements in only a few minutes, even in patients who may have

difficulty performing spirometry. The tremoflo software even automatically recognises and excludes data with outliers that can be caused by artefacts such as swallowing or leaks, and it further assists users by flagging potential sources of inaccuracies such as increased intra-measurement variability.



Figure 1.

measurements of oscillatory resistance to conventional outcomes, essentially trying to establish Oscillometry as an easier surrogate to spirometry or body plethysmography, we now understand that a key strength of Oscillometry lies in that it does not perfectly correlate with any of the conventional outcomes: rather than duplicating information that is already available through other techniques, there is increasing evidence that Oscillometry may provide important new information that is not readily obtained from the standard tools already found in a typical PFT lab.

Small Airways

One of those key benefits of Oscillometry is in providing outcomes that may relate to small airway function. In their 2014 review, McNulty and Usmani¹ write that "the small airways are frequently involved early in the course of lung diseases, with significant pathologies demonstrable often before the onset of symptoms or changes in spirometry and imaging." Dr Usmani, Reader in Respiratory Medicine and Consultant Physician at the National Heart and Lung Institute, Imperial College London & Royal Brompton Hospital, further explains⁵ that in the airway tree, "the large airways represent the trunk and bigger branches, and the small airways are like the much smaller branches

Last but not the least, a constantly growing stream of new research that emerged over the past two decades has deepened our understanding of the measurements offered by Oscillometry and how they correlate with pathologies of the respiratory system.¹⁻⁴ While much of the initial research was focussed on correlating

Fast, Easy Measurement

A gentle oscillation is superimposed on the patient's quiet breathing.

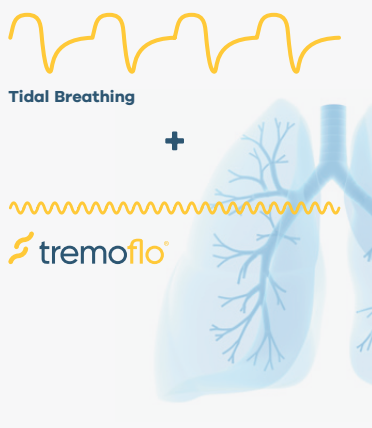


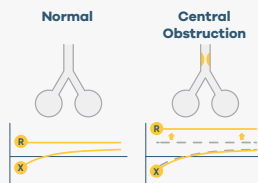
Figure 2.

In a 2009 study by Yamaguchi et al.,⁶ differences between groups receiving standard and novel finer particulate inhalers were identified with statistical significance by Oscillometry only, and missed by Spirometry.

extending into the leaves. In COPD, we call those small airways 'quiet' or 'silent' — not because they actually are, but because our listening tools haven't been that sensitive to pick up the noisy disease of COPD." As a result, the diagnosis of lung diseases such as Asthma and COPD has traditionally relied on a combination of symptoms and conventional lung function tests using spirometry that primarily identify the large airways and leave problems in the small airways undetected.

Characteristic Patterns

R Resistance curve X Reactance curve



Key Outcomes

R_5	Normal	↑
R_{5-20}	Close to zero	Close to zero
AX	Normal	Normal
$X_{5, \text{in-ex}}$	Close to zero	Close to zero

R_5	R_{5-20}	AX	$X_{5, \text{in-ex}}$
Resistance at 5 Hz	Reactance area	Resistance change, 5 to 20 Hz	Reactance difference insp-exp.

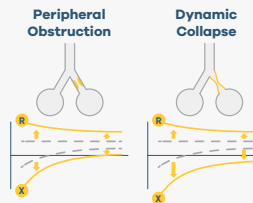
Figure 3. Characteristic patterns of Resistance (R) and Reactance (X) and typical interpretations, according to Komarow et al.⁷

patients who are at risk for losing asthma control, and in assisting with clinical decisions and treatment plans."

Indeed, with the recent advance of ultra-fine particle inhalers, efficient assessment of small airway function has the potential of translating quickly into treatment decisions. While traditional inhalers typically produce fairly large particles that are deposited primarily in the larger central airways, newer ultra-fine particles reach deeper into the lung periphery. In their 2009

Characteristic Patterns

R Resistance curve X Reactance curve



Key Outcomes

R_5	↑	↑
R_{5-20}	↑	↑
AX	↑	↑↑
$X_{5, \text{in-ex}}$	Small	↑

R_5	R_{5-20}	AX	$X_{5, \text{in-ex}}$
Resistance at 5 Hz	Reactance area	Resistance change, 5 to 20 Hz	Reactance difference insp-exp.

Figure 4. Characteristic patterns of Resistance (R) and Reactance (X) and typical interpretations according to Komarow et al.⁷ and Vassiliou et al.⁸

Characteristic Patterns

Getting back to the basics of the technique, Oscillometry effectively provides an indication of how much force the respiratory muscles need to produce to move air in and out of the lungs, ie how "hard" it is to breathe. Just like in other techniques, the primary outcome is a graphical representation of the data, more specifically a set of two curves called Resistance (R) and Reactance (X). Because the oscillatory waveform contains a multitude of frequencies (from 5 to roughly 40 Hz) that are simultaneously superimposed on the patient's quiet breathing, R and X are typically expressed in a single coordinate system with the frequency of oscillation on the horizontal axis.

Technically speaking, the Resistance curve reflects energy dissipation during breathing, eg due to resistance of airways to flow, whereas the Reactance curve reflects energy conservation in the lungs, notably including the compliance of those parts of the lungs that readily communicate with the airway opening. In more practical terms, the pair of R and X curves have been found to form four distinct characteristic patterns:^{7,8}

- In **normal subjects**⁷ (left graph Figure 3), the Resistance curve is a low, flat line. The normal Reactance curve typically has a small negative value at the lowest frequency, but rapidly crosses zero and remains positive for most of the range.
- In the presence of a **central obstruction**⁷ (right graph Figure 3), the Resistance curve is shifted upwards but remains a horizontal line, while Reactance is unchanged.
- In the presence of **peripheral obstruction**⁷ in the small airways (left graph Figure 4), the Resistance curve shows a distinctive shape that slopes downward from left to right, i.e. showing decreasing resistance with increasing frequency. Moreover, the reactance curve is shifted downward, crossing the zero line much further to the right.
- In patients with **dynamic airway collapse**⁸ during spontaneous breathing (right graph Figure 4), the negative displacement of the Reactance curve is even more pronounced, leading to an even greater separation of the two curves.

Actual tremoflo Data



Pre/Post Test
Asthma Patient



COPD Patient

Figure 5.

identified as potential indicators of small airway dysfunction.^{1,3}

Moreover, a landmark study by Vassiliou et al.⁸ demonstrated that in the presence of dynamic airway collapse, the reactance curve is far more depressed during expiration than during inspiration. The parameter X5.in-ex reflects this phenomenon (right graph Figure 4) and may potentially “help discriminate between asthma and COPD.”¹

For most of the key parameters reported by the tremoflo, normal reference values are available for subjects as young as 4 years of age and throughout adulthood.^{9,10} Many outcomes are readily displayed in the tremoflo software on a green-to-red gauge scales that makes it easy to position the patient relative to the applicable limits of normal (Figure 5).

Finally, numerous studies have used Oscillometry to assess reversibility and hyperresponsiveness in asthma in paediatric and adult populations.^{3,9} Bickel et al.² summarize that Oscillometry “has been found to be useful in measuring response to bronchodilators, such as salbutamol and ipratropium, in patients with asthma and COPD.” The tremoflo software supports pre/post testing workflows, visualization and reporting (Figure 5 top).

What's Next?

In summary, Oscillometry over the past decade has progressed from a marginal research tool to a technique that is sufficiently mature and increasingly validated to warrant more widespread adoption.

Clearly, one cannot expect Oscillometry outcomes to “feel familiar” from day one in the same way that flow-volume loops and FEV1 do. Oscillometry remains new and unknown to most clinicians, and as for any other new tool, some effort must be invested before a level of intimate familiarity can be achieved. However, we believe the benefits of a fast, easy lung function measurement obtained during tidal breathing, possibly coupled with the potential ability to obtain information about the highly important small airways, should easily warrant this investment.

As device manufacturers specialized in this field, we will continue to strive to make Oscillometry devices even smaller, cheaper and more accessible to a wide range of doctors, health care professionals and patients. In the meantime, we hope that the benefits demonstrated to date will arouse the curiosity of healthcare professionals who routinely screen, diagnose and monitor patients suffering from diseases that may affect peripheral lung function, such as Asthma and COPD. Together, we can continue to develop the collective insights and understanding that we believe will ultimately make Oscillometry a primary tool for all levels of pulmonary medicine.

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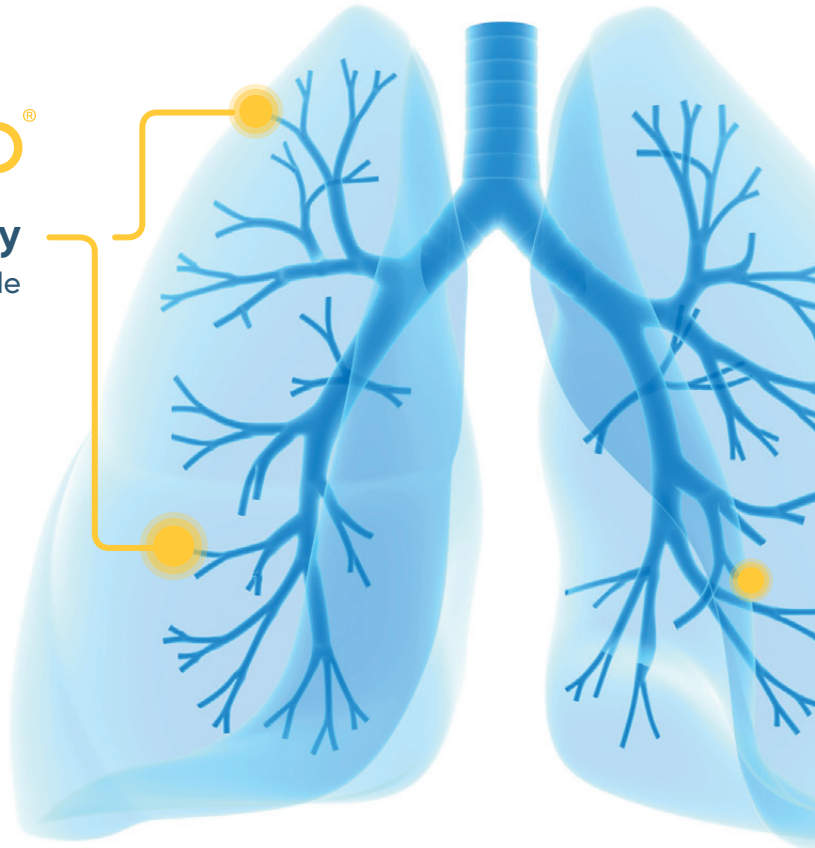
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Shaping New Perspectives on Pulmonary Function



Airwave Oscillometry

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The tremoflo C-100 provides information related to the small airway function.

"The small airways are frequently involved early in the course of [asthma and COPD] diseases, with significant pathology demonstrable often before the onset of symptoms or changes in spirometry and imaging."

McNulty and Usmani, ECRJ 2014

Comparison of SpO₂ / FiO₂ Ratio to PaO₂ / FiO₂ Ratio in Pediatric Patients as a tool to Determine Acute Lung Injury, RDS, and Extubation Readiness

Christopher J Moore, BS, RRT-NPS, RRT-ACCS, RPFT, AE-C¹, Kelly J Cresci, MS, RRT-NPS², and Jove Graham, PhD³

Abstract

Purpose: Limited studies show that a correlation between pulse oximetry (SpO₂) to fraction of inspired oxygen (FiO₂) ratio (SF) and partial pressure of oxygen dissolved in arterial blood (PaO₂) to FiO₂ ratio (PF) does exist. However, no set clinical ranges or criteria have been established for SF ratio. This retrospective study compared SF ratio to established Berlin Criteria for partial pressure of oxygen dissolved in arterial blood (PaO₂) to FiO₂ ratio (PF) to determine parameters or ranges for non-invasive assessment of extubation readiness, hypoxemia, and respiratory distress syndrome (RDS) severity in our pediatric intensive care unit population.

Methods: 718 arterial blood gas (ABG) data samples were collected in our pediatric critical care population. A linear regression model was used to find mean SF ratios and 95% prediction intervals that correspond with PF ratios in normal, moderate, mild and severe categories. Patients with a medical history of congenital or cyanotic cardiac defect, either repaired or unrepaired, were excluded as their total blood oxygenation is falsely low due to an unorthodox circulatory pattern.

Results: Of the four PF ratio severity categories, corresponding SF ratios in the severe and moderate ranges had the strongest relationship to PF ratios. Although the SF ratio increases in relationship to PF ratio increase, there is overlap among moderate, mild, and severe categories. Despite some overlapping of RDS severity categories, our study results conclude that SF ratio can be used as an effective and non-invasive assessment tool for oxygenation in pediatric patients with moderate or severe respiratory distress syndrome.

Introduction

When assessing a pediatric patient's oxygenation status, normoxemia is commonly referred to as arterial partial pressure of oxygen levels (PaO₂) levels within the range of 80 to 100 mm Hg in the blood, at sea level. It is common, however, to find varying degrees of lower blood oxygen levels within a hospital census. An oxygen value in arterial blood less than 80 mm Hg is referred to as hypoxemia. Hypoxemia may occur by many causal factors including trauma, sepsis, blood or anatomical

abnormalities, and exercise. There are three degrees of hypoxemia.

Table 1. Severity of hypoxemia per PaO₂ value¹

Degree of Hypoxemia	PaO ₂ range
Mild	60-79 mm Hg
Moderate	45-59 mm Hg
Severe	<45 mm Hg

If hypoxemia persists, hypoxia or decreased oxygen at the cellular level can occur. Mild hypoxemia is, however, unlikely to cause any detrimental hypoxic effects as arterial oxygen saturation remains at 90%, due to its exponential relationship to PaO₂, which is adequate for cellular oxygenation.

Developed during the mid-1970s in Japan, pulse oximetry is a noninvasive method that works by light absorption and reflected light through a sample of blood. This process is known as spectrophotometry. This measured value of light absorption is known as pulse oximetry, oxygen saturation, or SpO₂. SpO₂ has since become the premier noninvasive method to quickly assess hypoxemia. Limitations of using pulse oximetry include motion artifact and exposure to fluorescent lighting which can affect correctness of patient's SpO₂ value.² Because of artifact associated pulse oximetry, it may be difficult to account for acute hypoxemic events.³ Since pulse oximetry is also dependent on adequate perfusion, patients with signs of hemodynamic instability may require an arterial blood gas to monitor PaO₂ values.⁴

Originally defined in 1994 at the American-European Consensus Conference, the Berlin criteria/definition of PF ratio for RDS, listed in table 2, has long been the gold standard for quickly determining severity of both lung impairment and hypoxemia. Berlin criteria classification requires an arterial blood sample via either arterial puncture or arterial line draw and the FiO₂ administered to the patient.

Table 2. RDS severity per Berlin Criteria PF ratio^{5,6}

RDS Severity	PaO ₂ / FiO ₂ range
Severe	<100
Moderate	100-200
Mild	200-300
Normal	>300

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However, with a continual push to decrease both hospital-acquired infections and laboratory costs, the practice of using arterial lines routinely has continually diminished in the present era of medicine. Complications from either method of arterial sampling can include infection, emboli, pain, vascular occlusion or trauma, arteriospasm, hemorrhage, and nerve damage.¹ In looking at total cost during a PICU admission, laboratory studies accounted for almost 20% of the total expense.⁷

Used often in pediatrics are capillary blood gas analysis to assess a child's acid-base and ventilator status (ie pH and PCO₂). However, patient oxygenation status cannot be accurately measured via capillary sample since patient perfusion is variable and the sample is not anaerobically collected.¹ Because current trends in healthcare are geared to decrease both hospital-acquired infections, such as those from infected arterial line sites, and cost, the study results will be significant because it will allow us to assess a pediatric patient's oxygenation status non-invasively. PF ratio requires an arterial blood sample from either an arterial line or arterial puncture, whereas, SF ratio only requires a pulse oximeter reading from the patient.

An alternative and non-invasive method to assess lung impairment is through SF ratio which requires pulse oximetry and FiO₂ used by the patient. Prior studies have shown there is a solid correlation between SF ratio and PF ratio with a correlation coefficient of 0.72 and 0.85.^{8,9,10} However, specific SF criteria have not been defined to date, such as Berlin criteria with PF ratio, to determine correlating ranges. The greatest benefit of using SF ratio clinically is that the practitioner can monitor a pediatric patient's oxygenation status quickly, but also non-invasively.¹¹

This study explored the relationships between a child's RDS severity and SF ratio in relation to subsequent respiratory status. It represents the first phase of a goal to establish severity ranges for RDS in pediatric patients using the SF ratio.¹² The finding may provide information to quickly and noninvasively assess a child's oxygenation status in effort to treat fast onset lung pathology more effectively or liberate a patient from mechanical ventilation.

Methods

718 arterial blood gas samples from 32 PICU patients ranging in age from infant to 17 years of age were reviewed and PF ratio was calculated for each sample. The average blood gas sample per patient was approximately 22 samples ($n = 22.44$) with a range of 1 to 59 samples per patient. The patient's SpO₂ value was then collected from their vital signs flowsheet in the electronic health record (EHR) and was recorded at the same time each ABG was collected, ± 15 minutes, and SF ratio was calculated. Since the possibility of some variability can exist between pulse oximetry arterial blood saturation, collected SpO₂ and SaO₂ values were within $\pm 3\%$ of each other.

These values were then entered into an Excel worksheet and scatterplots and regression modeling were completed using the PF and SF ratio data. Statistical analysis was performed using Microsoft Excel (Redmond, WA) and R 3.0.3 (Vienna, Austria) software. PEEP values were also collected in 496 of the 718 samples. Samples that included PEEP data were then divided into two categories of < 7 PEEP and ≥ 7 PEEP and linear regression assessment was completed. Mean predicted

values for SF ratio were then calculated for each severity category of PF ratio.

Results

Figure 1 shows the relationship between SF and PF for all observations, including 6 observations with extremely high PF ratios (> 900 mm Hg). The slope of this regression line is 0.35 ($p < 0.001$) so there is a statistically significant positive relationship between PF and SF ratios, and for every 100-unit increase in PF ratio, we predict that the SF ratio should increase, on average, by 35 units (95% confidence interval (CI) = 31 to 38 units). We note a high degree of residual error around the prediction line, which means that knowing the PF value would usually predict the exact value ± 167 units (± 2 residual standard errors).



Figure 1. SF ratio (red) vs PF ratio (blue) for all sample observations. The best-fit line ($y = 0.3688x + 144.19$, $R^2 = 0.3602$) represents SF ratio data points revealing positive relationship to PF ratio.

Prior studies comparing PF and SF ratios reveal the strongest correlation when PF is less than 200. (Bilan 2015). However, the data in this investigation revealed a stronger PF / SF relationship when PF ratio was < 300 ($r = 0.76$) vs $PF < 200$ ($r = 0.71$). Figure 2 is the same plot type as Figure 1, but using only the data where PF ratio was ≤ 300 . In this case, the slope of the regression line is 0.86 ($p < 0.001$) and 95% CI = 77 to 94 units, indicating a both a stronger and statistically positive correlation ($r = 0.76$) between SF and PF ratio. There is less variability in SF ratio and PF ratio when each number is small. Looking at both scatterplots, as the PF ratio increases, there is more scatter from the regression line. This can be explained in that it is possible to have the same SpO₂ value in two patients, but their PaO₂ value can be markedly

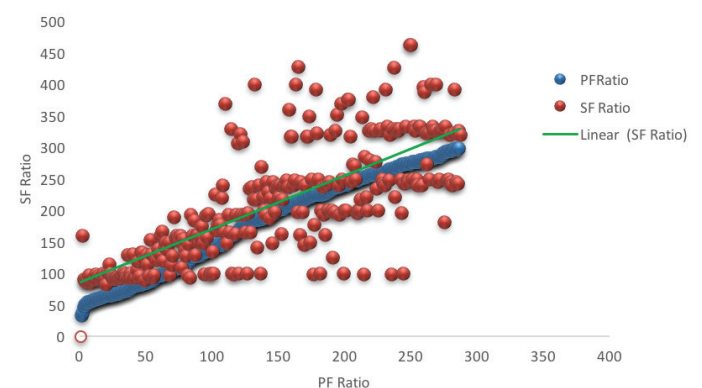


Figure 2. SF ratio (red) vs PF ratio (blue) for all observations where PF ratio was < 300 revealing a statistically stronger positive relationship when compared to SF ratio. As PF ratio increases, more SF ratio data scatter is seen. The best-fit line ($y = 0.8521x + 84.737$, $R^2 = 0.5707$) represents SF ratio data points where PF is < 300 .

different. However, when the PF ratio is less than 300 and using a 95% confidence interval, the SF ratio increases by 86, on average, for every 100-unit increase in PF ratio.

RDS Severity Categories and Overlap

Data collected was divided in to RDS severity categories per Berlin Criteria. Although all categories revealed positive correlation between SF and PF ratios using the Pearson product-moment correlation coefficient, severe and moderate RDS classes exhibited the strongest relationship with $r = 0.57$ and 0.41 , respectively, noted in Table 3. Data points comparing PF vs SF ratio among RDS categories are shown in Figures 3 through 6.

Table 3. Pearson product correlation coefficient and mean calculated SF ratio values in comparison to mean calculated PF ratio classified by Berlin criteria. Severe RDS classification shows the strongest positive relationship among PF vs SF ratio data.

RDS Severity	n	(r)	SF Mean	PF Mean
Normal	361	0.26	286	440
Mild	174	0.26	262	253
Moderate	106	0.41	175	149
Severe	75	0.57	106	74

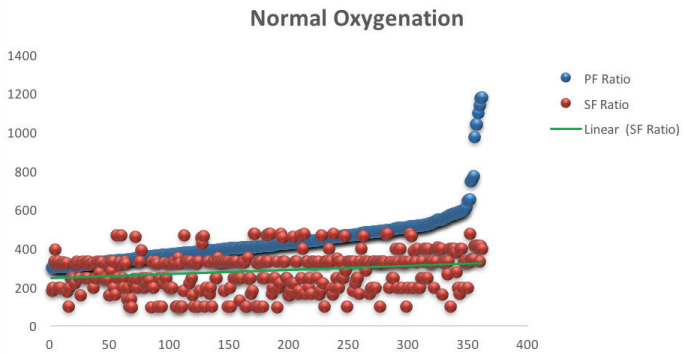


Figure 3. SF (red) and PF (blue) ratio data points representing normal oxygenation per Berlin Criteria. The best fit line ($y = 0.2122x + 247.98$, $R^2 = 0.0526$) represents SF ratio data points among PF ratio classification for normal oxygenation.

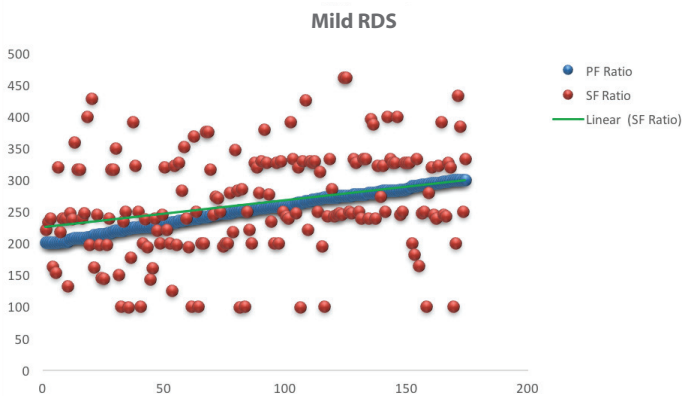


Figure 4. SF (red) and PF (blue) ratio data points representing mild RDS classification per Berlin Criteria. The best fit line ($y = 0.4245x + 225.84$, $R^2 = 0.07$) represents SF ratio data points when compared to corresponding PF ratio data points in the mild RDS category.

Mean calculated SF ratio values and ranges (95% prediction interval) in comparison to PF ratio Berlin criteria are listed in Table 4. Mean predicted SF ratios do increase as PF ratio increases. Figure 7 and Table 5 represent PF ratio among our data using Berlin Criteria. When PF ratio is compared to SF ratio

data (Figure 8 and Table 6), a high degree of overlap is seen in SF ratio among all RDS categories classified via Berlin Criteria. Therefore, our results suggest that it is likely that there will be patients whom would fall into normal, mild, moderate, and severe PF ratio RDS categories that could all have the same SF ratio value.

Table 4. Mean and 95% prediction interval for SF ratio when comparing Berlin Criteria PF ratio data set to corresponding SF ratio data.

RDS Severity	n	SF Mean	PF Mean	Mean and 95% prediction interval for SF ratio Corresponding to PF Ratio RDS Category
Normal	361	286	440	286 (96-477)
Mild	174	262	253	262 (105-419)
Moderate	106	175	149	176 (59-292)
Severe	75	106	74	107 (65-149)

Table 5. Mean values and ranges for PF ratio data set classified by RDS category.

PF Ratio	Severe	Moderate	Mild	Normal
Min	33	100	201	302
Mean	74	149	253	440
Max	99	197	300	657

Table 6. Mean values and ranges for SF ratio data set classified by RDS category.

SF Ratio	Severe	Moderate	Mild	Normal
Min	83	93	99	97
Mean	106	175	262	286
Max	160	269	462	476

Table 7. PF and SF ratio data ranges and mean values categorized by PEEP vs no PEEP.

	SF Ratio without PEEP	SF Ratio with PEEP	PF Ratio without PEEP	PF Ratio with PEEP
n	222	496	222	496
min	83	88	33	57
mean	196	267	229	349
max	426	476	750	657

PEEP

In comparison of 496 ABG samples in which PEEP data was collected, figure 10 represents PF and SF ratio regression model comparing those samples with $PEEP < 7$ ($n=338$ samples) and $PEEP \geq 7$ ($n=158$ samples). There was not a significant difference between these groups when comparing SF to PF ratio correlation. Each group shows a very high amount of overlap in data plots. A significant difference, statistically, does not exist in the slope (0.27 vs 0.25 , $p = 0.75$) of the regression line or the y intercept of the trend lines for each group, illustrated in Figure 10, although mean PF and SF values were increased in the data group where $PEEP \geq 7$.

PEEP levels did not change the relationship between SF and PF ratios in this investigation reaffirming Pandharipande’s study in

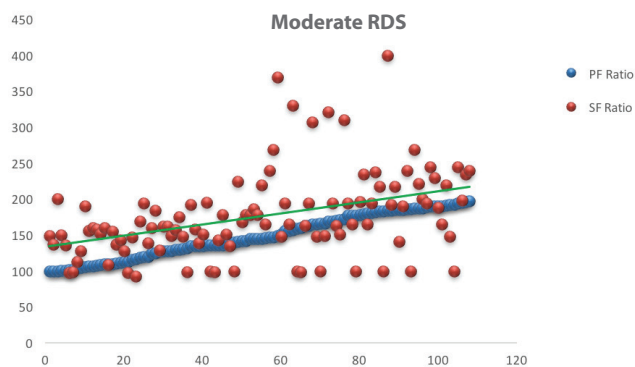


Figure 5. SF (red) and PF (blue) ratio data points representing moderate RDS per Berlin Criteria. The best-fit line ($y = 0.7677x + 133.73$, $R^2 = 0.1679$) represents SF ratio data points when compared to corresponding PF ratio data points in the moderate RDS category

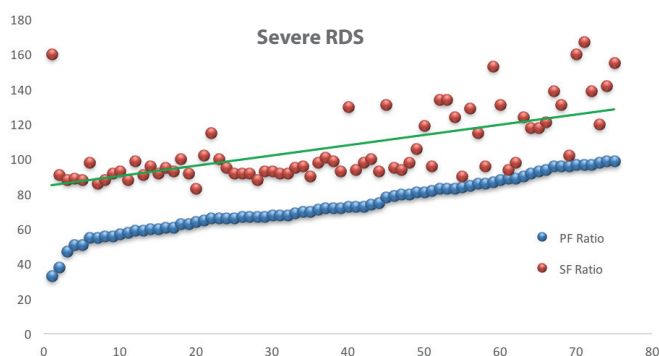


Figure 6. PF ratio (blue) and SF ratio (red) data points representing severe RDS per Berlin criteria classification. This category shows the strongest relationship between SF and PF ratio among all RDS categories. The best-fit line ($y = 0.5828x + 84.626$, $R^2 = 0.3718$) represents SF ratio data points when compared to corresponding PF ratio data in the severe RDS category.

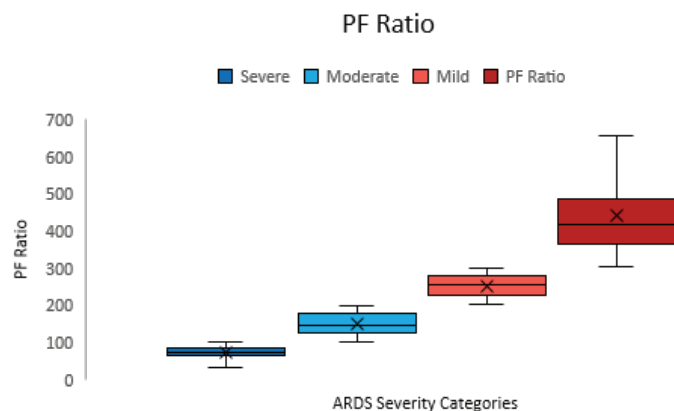


Figure 7. PF Ratio data set classified by RDS category (Berlin Criteria).

2009.¹³ With both groups of PEEP data combined, the SF ratio increases a mean value of 29 units for every 100-unit increase of SF ratio (95% confidence interval = 24 to 34 units, $p < 0.001$). Figure 11 compares samples from subjects whom did versus did not have PEEP data recorded. Both PF and SF groups with PEEP recorded showed statistically higher mean values for both SF and PF ratios.

Discussion

Age

Results of this investigation are based exclusively on recorded FiO_2 , PaO_2 , SpO_2 , and PEEP values. Limitations of this study exclude variables such as temperature, patient positioning, pulse oximetry probe placement, and SpO_2 values $\geq 97\%$ in which the

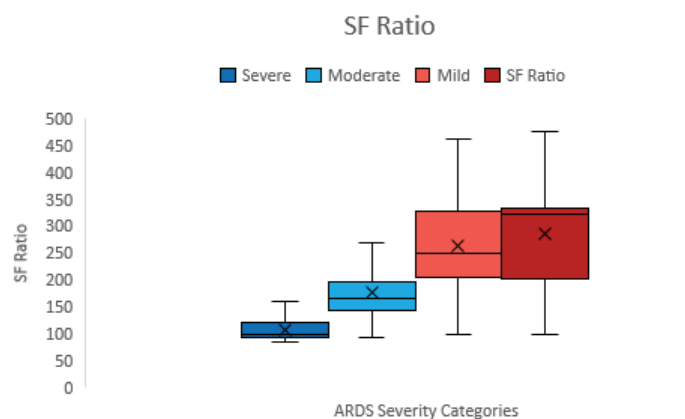


Figure 8. Overlap of RDS categories when using SF Ratio in comparison to PF ratio.

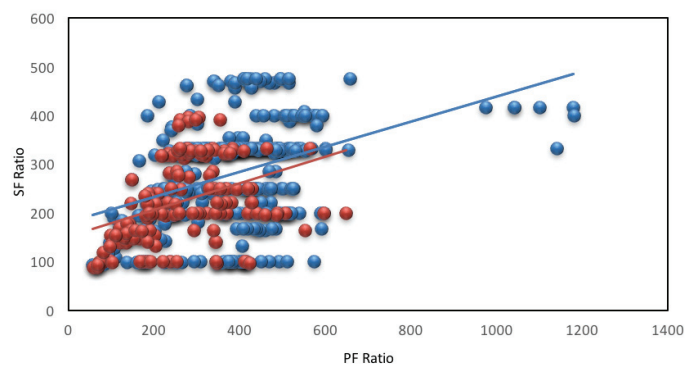


Figure 10. SF ratio vs PF ratio for patients who had PEEP values recorded, stratified by those with PEEP < 7 (blue) vs PEEP ≥ 7 (red). No significant statistical difference exists between the slopes of each best-fit line among each group.

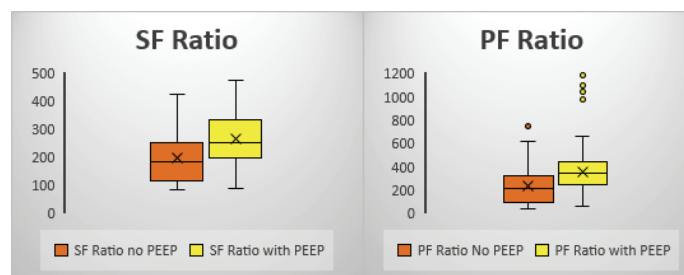


Figure 11. Comparison of SF and PF ratios with and without PEEP. Each group with PEEP measurements showed statistically higher mean values for SF and PF ratio.

oxyhemoglobin dissociation curve begins to plateau.¹⁴ Outlier data was not eliminated as these are values that a clinician may very well encounter in daily practice. Patient age was not clinically significant for this investigation. Although PaO_2 does decrease 5 mm Hg for every 10 years of age due to the exponential relationship that exists between PaO_2 and SaO_2 , the data values used in this study would be unaffected due to this study being limited to a pediatric population.¹

In pediatric patients with a cyanotic cardiac defect (i.e. right to left shunt), deoxygenated blood from the right side of the heart mixes with oxygenated blood from the left side. As a result, PaO_2 , SaO_2 , and SpO_2 will all have lower values due to this irregular circulatory process. Since right to left shunt lowers oxygenation levels, patients with either surgically corrected or uncorrected congenital cardiac defect were excluded from data collection.

Berlin Criteria vs current standards

In 2015 RDS classification was reevaluated for the pediatric population. Current recommendations for pediatric acute respiratory distress syndrome (PARDS) classification require oxygen index (OI) for classification during invasive mechanical ventilation. However, PF ratio was used for this investigation since 1) it can be quickly calculated for patient oxygenation assessment. 2) not all ABG samples used in this investigation were drawn while on mechanical ventilation, but rather, oxygen delivery devices with definitive FiO₂ settings such as high flow nasal cannula or aerosol face mask / tracheostomy collar. Hence, PEEP or mean airway pressure values on these samples were unable to be measured or recorded.

PF ratio

There are, of course, advantages and disadvantages of using PF ratio in the clinical setting. Advantages include that PF ratio can be calculated quickly and it does not require a mean airway pressure value as oxygen index does allowing it to be calculated using any oxygen device that has a defined and specific FiO₂.

However, PF ratio can often place all patients in to one large group and does not look at individual variables among patients such as severity of lung injury. Also, practitioners do not always practice the same mechanical ventilation principles and management. Lastly, PEEP changes can alter PF ratio.¹⁵

Sample size

Arterial blood gases via puncture and arterial lines are not used as prominently as they were 20 years ago. At that time, in the hospital setting, if one adjusted mechanical ventilator or oxygen delivery device settings, the practitioner would then draw an arterial blood gas sample to assess those changes. With the emergence of noninvasive monitoring methods for oxygenation (SpO₂ and transcutaneous oxygen (TCPO₂)) and ventilation (end-tidal carbon dioxide (PETCO₂)) and transcutaneous carbon dioxide (TCPCO₂), arterial blood gasses are not drawn as frequently as they once were. Infection, tissue and nerve trauma, edema, and hemorrhage / hematoma are some possible adverse effects of direct arterial sampling. Thus, this investigation necessitated using multiple samples from the same subject. However, multiple RDS severity categories were represented among the data.

Extubation readiness

Since this investigation reveals overlap of SF ratio in all Berlin Criteria RDS categories when compared to PF ratio, it tends not to be an adequate measure of oxygenation status when evaluating a patient from liberation from mechanical ventilation. Extubation would typically occur when the patient falls into either mild RDS or normal Berlin criteria classification. These two categories, however, showed the highest amount of SF overlap in our results making it difficult to non-invasively assess patient oxygenation accurately.

Conclusion

Our results conclude that SF ratio can be used as noninvasive assessment tool of oxygenation in pediatric patients, especially in the severe to moderate RDS categories, although PF ratio continues to be widely used to measure oxygenation and RDS severity. Due to overlap of SF ratio values in all RDS categories, a practitioner should use sound clinical judgment when using SF ratio to evaluate patient oxygenation status. SF ratio may assist in quick recognition of pediatric patients that are at higher

risk for RDS. However, due to high overlap in mild to normal RDS categories, SF may not be the best assessment tool to help determine accurately oxygenation to assist in assessment of extubation readiness in our pediatric population.

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Keys to Success: A Pediatric Respiratory Therapy Case Study

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Throughout infancy and childhood, gross and fine motor development progresses in a typical pattern and timeline which impacts many aspects of a child's life. However, when infants and children are tracheostomized at a young age, this developmental process is negatively impacted. Placement of a tracheostomy tube in the child's airway opens a previously closed respiratory system. While the tracheostomy is necessary to improve the respiratory status of the child, having a tracheostomy tube in place changes the dynamics of the aerodigestive tract. The child now breathes through the tracheostomy tube and does not use the upper airway efficiently, especially if the tracheostomy tube cuff is inflated. This loss of airflow through the upper airway diminishes or eliminates stimulation of the upper airway, causing changes in sensation, loss of subglottic pressure, negative impacts on secretions and secretion management, changes in swallow function, and loss of voicing. In addition, having an open system has been shown to have a negative effect on trunk support and core stability for mobility (Massery, 2014, 2006; Massery, Hagins, Stafford, Moerchen, & Hodges, 2013). Early intervention is imperative, as a disruption during this critical period may have significant impacts on a patient's development, in particular to language and speech (Stevens, Finch, Justice, & Geiger, 2011). The sooner the clinical team is able to intervene, the risk for long-term delays is decreased (Hofmann, Bolton, & Ferry, 2008).

Application of the Passy Muir Tracheostomy and Ventilator Swallowing and Speaking Valve® provides opportunities to close the system and restore airflow to the upper airway. The Passy Muir Valve® is a bias-closed position, no-leak speaking valve that closes at the end of inspiration and remains closed throughout the expiratory cycle. By doing so, it allows a patient to breathe out through the mouth and nose, returning airflow to the upper airway and restoring functions that were compromised when a tracheostomy tube was placed. Two of those compromised functions critical to a young child's development are vocalizing and swallowing.

Respiratory therapists (RT) work with these children to enable them to eat and communicate again, but the primary focuses of the RTs are: (1) how can we wean this patient; and (2) where

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Lyndsi Yarkosky with pediatric patient Noah. Photo submitted.

do we begin? Within The Children's Institute of Pittsburgh, the respiratory therapists use the Passy Muir Valve to assist with decreasing ventilator settings, decreasing or eliminating oxygen use, increasing trials off the ventilator, and as a stepping stone towards the discontinuation of mechanical ventilation in the decannulation process. Use of the Passy Muir Valve involves written policies, procedures, and guidelines. In addition, the clinical approach and techniques used for weaning and decannulation are used by the multidisciplinary team and are key contributions to success with the patients.

The human body is intended to be a closed system and when a tracheostomy is placed, the system becomes open. Typically, exhalation occurs against resistance which provides for physiologic Positive End Expiratory Pressure (PEEP). PEEP is the amount of pressure that remains in the lungs at the end of exhalation to ventilate the alveoli and keep them from collapsing. Placement of a tracheostomy tube in the trachea causes an opening within the airway, which punctures the naturally closed and pressurized system. With an open system, the body cannot maintain a strong, natural PEEP. PEEP is important to maintain as it improves oxygen saturation levels, improves gas exchange, and restores Functional Residual Capacity (FRC — the normal

volume of gas left in the lungs after exhalation) (Vanderford, 2002). When a patient is on mechanical ventilation, the ventilator may be used to supplement physiologic pressures by setting a PEEP (normal PEEP is 3-5 cmH₂O) (Deakins and Myers, 2007). If a patient is off the ventilator but has an open system, then the ability to sustain sufficient PEEP is compromised and may impact oxygenation and work of breathing.

In addition to changes in PEEP, an open system impacts the ability to have an effective cough. A more effective cough is produced with a closed system, which also facilitates secretion management. Applying the bias-closed position, no-leak Passy Muir Valve to a tracheostomy tube closes the system, which returns the lungs to a more normal physiologic process (Sutt, Caruana, Dunster, Cornwell, Anstey, & Fraser, 2016). Using the Valve enables the patient to breathe through the upper airway during exhalation, which returns the respiratory system to a more normalized physiologic process and allows the patient to have restored physiologic PEEP by using the normal resistance of the vocal cords and upper airway. In order to restore this more naturalized system, patients with tracheostomies must first be evaluated for Passy Muir Valve candidacy.

Closing The System Evaluation

For valve use, patients with tracheostomies should be evaluated by the speech-language pathologist (SLP) and RT. If the patient is on a ventilator, the RT evaluates for stable ventilator settings, such as a FiO₂ < 60%, PEEP < 10 cmH₂O, and Peak Inspiratory Pressure (PIP) < 40 cmH₂O. The first parameter assessed is the medical stability of the patient, with the team considering if the patient is stable and appropriate to consider cuff deflation and potential Valve use. The patient also should be awake, alert, and attempting to communicate. Next, if the patient has a cuffed tracheostomy tube, tolerance of cuff deflation is assessed. After oral and tracheal suctioning, the RT uses slow cuff deflation, allowing the upper airway to become acclimated to the different sensations as airflow is returned to the upper airway (Hess & Altobelli, 2014).

The next critical step is to ascertain that the upper airway is patent. Airway patency may be evaluated in one of two ways if the patient is on the ventilator: (1) by checking that airflow is going around the tracheostomy tube, up through the vocal folds, and out the nose and mouth by feeling for airflow or hearing a cough, throat clear, or vocal sound; and (2) checking for a change in the PIP. If PIP decreases when the cuff is deflated, this decrease indicates a leak through the upper airway. Once a Valve is placed in-line, tidal volume (V_t) can be used to slowly return patient to their pre-cuff deflation PIP by increasing V_t in small increments until at pre-cuff deflation PIP. If all of these factors are positive, then the team begins looking at the application process.

Keys to Successful Application

Step One: Building Trust

A key first step in the approach to placing a Passy Muir Valve, whether the patient is on or off the ventilator, is building trust. Throughout the course of a typical hospital stay, a child interacts with many team members, who perform different procedures or introduce new treatments. It can be overwhelming for the parents or caregivers and intimidating to the children. Bonding and building a relationship with the family sets everyone up for success. When the parent or caregiver is comfortable and

trusting of a new face, the child is less likely to be anxious or fearful. Establishing rapport and a level of trust among all of the participants is critical to a successful approach.

Step Two: Providing Education

Another crucial step in the keys to success is education; making sure the parent or caregiver is on board and understands the benefits of the Passy Muir Valve. In addition to speech and swallowing, education about additional benefits, such as secretion management and restoring physiologic pressure should be provided. Everyone also should have a good understanding of what steps will be taken during the assessment.

Various techniques for providing education may be used. Any member of the team, from the SLP to the RT, will be involved in education. Resources specific to pediatrics and the Passy Muir Valves are available through the Toby Tracheosaurus™ Program from Passy-Muir, Inc. and the TRACHTOOLS™ App. These provide different methods to approach education, from using a stuffed animal with a tracheostomy to showing sample patient videos.

Step Three: Use of Distraction

The final key to success when placing a Passy Muir Valve is distraction. At times, when a child is stressed or anxious, being able to provide a distraction from the intended plan may assist with improving participation and increase the success rate. Options for distraction include age-appropriate activities, play, and changing the environment. If a hospital patient room has been the only environment, the child may benefit from going to the gym or to an outside area to experience new scenery. Another aspect related to distractions is to limit extraneous stimuli, such as noise and lights, which may have negative effects on the child's ability to participate.

One Child's Story

Noah is a 12-year-old male who presented to the Emergency Department on May 31, 2016 with weakness. His weakness was caused by a spinal cord stroke, with fluid pinching his spinal cord, preventing blood flow to his brain. The fluid accumulation stemmed from his underlying birth diagnosis of Chiari Malformation, a structural defect in the cerebellum at the level of the foramen magnum. Noah also had a history of migraines, asthma, and anxiety. He was admitted to the hospital, and surgery was performed to remove the fluid and decompress the spinal cord, but he remained paralyzed from the neck down as a result of the stroke.

During his hospital stay, Noah was tracheostomized on June 6, 2016 with a #4 Shiley Tracheostomy Tube Cuffed with disposable inner cannula. In need of intense rehabilitation, Noah was referred to The Children's Institute of Pittsburgh and transferred to the pediatric rehabilitation hospital on June 29, 2016. The team at The Children's Institute established several primary goals: (1) to wean him from his ventilator; (2) to provide education; (3) to train the patient and his mother; and (4) to initiate extensive therapies in the disciplines of physical therapy, occupational therapy, speech-language pathology, and respiratory therapy. In our facility, the multidisciplinary team consists of respiratory therapists, speech-language pathologists, recreational therapists, nurses, and physicians. We also consider the patient, family, and parent or caregiver an integral part of the team. In addition to the combined clinical skills of the multidisciplinary team, we focus on using the three keys to success: trust, education, and

distraction. The use of these techniques played a significant role in treating and weaning Noah, one of our recent challenging patients, who was dependent on a tracheostomy and ventilator.

At the time when the RT and SLP began working with Noah, he was on the Trilogy Ventilator with settings of: SIMV/PC, PC 22 cmH₂O (centimeters of water pressure), RR 16 bpm (breaths per minute), PEEP 8 cmH₂O, PS 8 cmH₂O and 2l pmO₂. SIMV (Synchronized Intermittent Mandatory Ventilation) is a common mode of ventilation that ensures the patient is getting the minimum set ventilation but also allows the patient to take spontaneous breaths. This mode is a moderate support mode. Pediatric patients may be ventilated with set pressures to achieve desired volumes, instead of set volumes, in order to help prevent barotrauma to the lungs (Dahlem & Randolph, 2015). At the time of admission, Noah was on a Pressure Control (PC) of 22 cmH₂O, which is a normal inspiratory pressure for the lungs, and his Respiratory Rate (RR) was set at 16 bpm. If he took additional breaths on his own above what the ventilator was supplying, a Pressure Support (PS) of 8 cmH₂O was set to give his spontaneous breaths a boost. This setting means that if Noah was breathing 20 bpm, 16 of those breaths would be at the PC 22 cmH₂O and the other 4 would be at a PS of 8 cmH₂O. His PEEP was set at 8 cmH₂O, and he was receiving 2 liters of oxygen via the ventilator. The initial goal of therapy was to deflate the tracheostomy cuff and wean the ventilator settings with consideration for Passy Muir Valve use.

Due to the patient's underlying issues with anxiety, the initial stages of cuff deflation and vent weaning presented a challenge. With the cuff still inflated, Noah was unable to vocalize and did not have easy access to communication with staff or family, which added to his frustration. Whenever a member of the team attempted to work with him, his respiratory rate and heart rate would increase as did his anxiety in response to possible change.

Our unspoken motto in the facility is "slow and steady wins the race." To set Noah up for success, the approach to his care included a variety of methods while instituting the keys to success. To increase the chance of success, the initial focus was on building trust, explaining the plan, and letting him begin to know the team members. Another consideration was to have his mother become involved with the therapies to help with his anxiety. Having his mother educated on the plan and providing support was a key element to success.

During this step, it was essential to maintain a consistent team. We also integrated his speech, respiratory, and recreational therapy into interdisciplinary treatment sessions, while pursuing cuff deflation and ventilator weaning. The team spent time taking Noah outside, and therapy began with sitting and conversing about his interests. Once he became comfortable, SLOW cuff deflation was initiated, allowing him to acclimate to the sensation of air moving through his nose and mouth — something he had not felt in a while. Typically, with patients, cuff deflation would occur over one to two minutes to avoid a rush of air into the upper airway. However, with Noah, it took approximately 10 minutes to get the cuff fully deflated. We did slow cuff deflation twice a day for three days, until he was comfortable with the change and with the team members who were working with him.

After we had successful tracheostomy cuff deflation, it was time to introduce the bias-closed position no-leak Passy Muir Tracheostomy and Ventilator Swallowing and Speaking Valve (PMV). Noah's ventilator settings were stable, he wanted to eat and speak again, and we had confirmed his upper airway was patent by hearing whispers of speech after his cuff deflation. However, the team met with similar obstacles when using the PMV as they had with cuff deflation. Noah was hesitant and anxious about something new, which impacted his breathing.

The first time we placed the PMV in-line with the ventilator, Noah agreed to use it for 10 minutes. Another consideration for success with children is to have them invested in the therapy and participate with planning the goals. While there was much hesitation from Noah, having him assist with the plan and understand it helped to motivate his use for 10 minutes. Using distraction, while providing encouragement, also assisted with increasing his time wearing the Valve. While it was not the easiest 10 minutes, Noah enjoyed having his voice back and being able to try tastes of Nutella. The ventilator settings for the initial Valve use were: SIMV/PC, PC 22 cmH₂O, PEEP 8 cmH₂O, PS 8 cmH₂O, RR 8 bpm. Alarms were set at low minute ventilation 0.5 L/min and circuit disconnect 5 seconds (high and low pressures are automatically set at 5 above and below in SIMV/PC mode). Due to the Trilogy Ventilator leak compensating in pressure modes, no changes were made to the settings or alarms.

Over the next week, Noah's use of the Valve steadily increased until he was using it all day. By this point, Noah also tolerated tracheostomy cuff deflation continuously, 24 hours a day. He was medically stable and appropriately ventilated with the tracheostomy cuff deflated because of the leak compensation with the Trilogy ventilator. To increase the space around his tracheostomy tube within the diameter of the trachea and avoid unnecessary complications of the tracheostomy cuff, he was transitioned to a cuffless tracheostomy tube. The change introduced a Shiley tracheostomy cuffless tube (4 DCFS). Since the Trilogy ventilator leak compensates when in pressure modes, having a tracheostomy cuffless tube or a valve laced in-line, does not change the ability of the ventilator to deliver the set pressure automatically. If the patient uses a different mode or a different ventilator, adjusting the pressure or volumes to pre-cuff deflation values would assist in compensating for the air leak.

Over the next two weeks, as Noah wore the PMV, his ventilator settings were weaned down to BiPAP settings (a spontaneous, weaning mode). After a period of time on the BiPAP settings, it was decided to trial the tracheostomy mask. The RT removed him from the ventilator and placed him on a room air tracheostomy mask with humidification. Within one minute, Noah's SpO₂ dropped from 98 to 87% and he was struggling to breathe. The RT bagged him, returning his SpO₂ to baseline, and placed him back on the ventilator. After several minutes on the ventilator, Noah's respiratory status returned to his pre-trach mask trial baseline, and he calmed. He stated that the feeling was so different off the ventilator that he was scared, and he could not talk, which added to his fear.

Because Noah had a negative experience during his first trial off the ventilator, it was a few weeks before he agreed to try again. The initial unsuccessful trial caused a setback for his weaning process. We provided more education to Noah about the change from a supported system on the ventilator and a closed system

when using the PMV in-line with the ventilator to an open system, and that his lungs lost pressure that the ventilator was previously providing him.

Additional education increased his comfort with the idea of being off the ventilator again. This time the plan incorporated a change in that Noah would transition from the ventilator to his PMV immediately, skipping the tracheostomy mask. The reason for this process was to provide a closed system immediately. Most importantly to Noah was that he would be able to talk, which would assist with lessening his anxiety. The second main reason to place the PMV immediately was so that his lungs did not lose pressure. As previously discussed, the lungs operate with PEEP under a closed system. When Noah was trialed with a tracheostomy mask and no PMV, he had an open system and could not sustain his own natural physiologic pressures. His oxygenation dropped, and he felt his breathing was compromised. The plan this time was to use the Passy Muir Valve immediately upon removal of ventilation, so that a closed system would be established.

With this plan, Noah had a successful trial. He was off the ventilator and used the PMV for 15 minutes during his first trial. Over the next month, his strength and endurance slowly increased, and Noah was off the ventilator for 2.5 hours, twice a day, at the time of discharge home. He was happy that he did not have to use his ventilator for the whole day while at school.

Achieving Success

Success with this patient did not come easily or quickly, however, by implementing our techniques of building trust, providing education, and using distraction techniques, our efforts with Noah were successful. It took patience and creativity on the part of the staff and a lot of trust and patience on Noah's end. Understanding from the beginning that we needed to be aware of our approach and take our time, helped us all in the long run.

We also now consider our best practice of tracheostomy mask trials. Working with Noah demonstrated to the team the need to have a closed system to establish use of a more natural physiologic PEEP and to return a patient's ability to use their upper airway. Closing the system also assists with sustaining a patient's oxygenation when transitioning to being off the ventilator. Transitioning from ventilator to tracheostomy mask has its own complications to consider and implementation of the PMV to maintain a closed system may assist with both patient comfort and improved respiratory support. It not only made a difference in how this patient felt, but it improved how his lungs responded to the change and to the weaning process.

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Effect of Inspiratory Time on PEF/PIF Ratio in Three Oscillating PEP Devices in an Adult Chronic Bronchitis Model

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Introduction

Oscillating positive expiratory pressure (OPEP) therapy is an airway clearance technique designed to help clear secretions from airways. One of the primary factors for effective secretion clearance is the ratio of peak expiratory flowrate (PEF) to peak inspiratory flowrate (PIF). It has been reported that in order to move mucus cephalad, the PEF must exceed PIF by 10% (PEF/PIF > 1.1), creating an expiratory flow bias.^{1,2}

Flow bias refers to the overall net movement of gas flow based on inspiratory and expiratory flowrates. As an analogy, two steps forward and one step back would be overall net movement forward whereas two steps forward and three steps back would be overall net movement backward. Likewise, a higher peak inspiratory flow than peak expiratory flow generates an inspiratory flow bias and therefore net movement of gas flow to the lung periphery. A higher peak expiratory flow than peak inspiratory flow generates an expiratory flow bias and therefore net movement of gas flow toward the oropharynx.

The primary purpose of this study is to examine what effect various inspiratory times have on expiratory flow bias and the PEF/PIF ratio produced by three oscillating PEP devices during simulated breathing: the vPEP (D R Burton Healthcare, Farmville, NC), the Aerobika (Monaghan Medical, subsidiary of Trudell Medical International, London, Ontario Canada), and the Acapella (Smiths Medical, Kent, United Kingdom). Any differences in PEF/PIF ratio between the three devices will also be examined. The secondary purpose is to evaluate any differences in flow amplitude, mean expiratory pressure, and the absolute value of peak expiratory flow between the three devices. The primary hypothesis is that as inspiratory time is prolonged, it will cause an increase in the PEF/PIF ratio and therefore improve expiratory flow bias. The secondary hypothesis is that there will be no differences in the PEF/PIF ratio, flow amplitude, mean expiratory pressure, and the absolute value of peak expiratory flow between the three devices.

Method

An IngMar Medical ASL 5000 lung simulator, v3.5 (Pittsburgh, PA) was used in the data acquisition and analysis. The instrument was programmed to simulate OPEP therapy in an adult chronic bronchitis patient with a lung compliance of 80 mL/

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cmH₂O and resistance of 30 cmH₂O/L/sec. Measurements were taken at four different inspiratory times: 1.33 seconds, 2 seconds, 4 seconds, and 6 seconds. A respiratory rate of 6 breaths per minute and a four-second, active exhalation was set for all measurements.

Inspiratory muscle pressure was adjusted to achieve a tidal volume of 1200 mL. The rationale for choosing this volume is based on two studies: a longitudinal study of COPD patients and another study of healthy volunteers. In the longitudinal study, 5,992 COPD patients were found to have a mean inspiratory capacity of 2.03 liters.³ In the other study, forty-two healthy subjects performing OPEP therapy achieved approximately 65% of their inspiratory capacity when asked to take a deeper breath than normal.⁴

Therefore, applying the values in two studies and adjusting for disease process, it is reasonable that the average COPD patient would be able to achieve a volume of approximately 1200 mL when performing OPEP therapy. Additionally, some instructions for use indicate that a patient should inhale at 2-3 times greater than a normal breath, which would result in approximately the same tidal volume that was used in this study.⁵

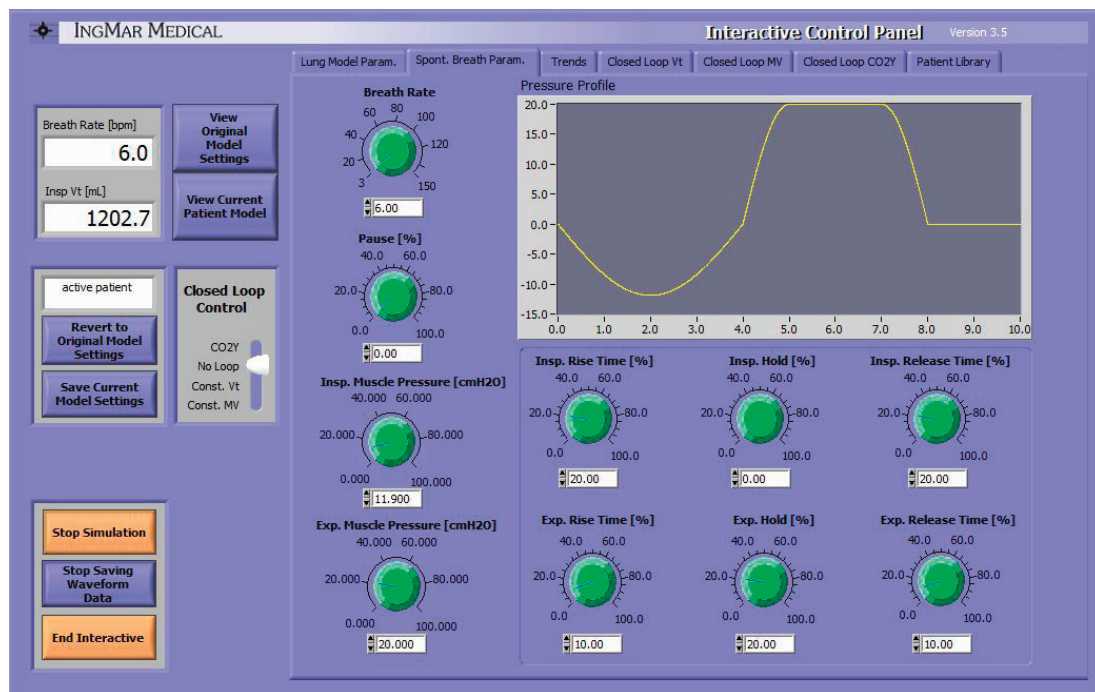
Complete instrument settings are shown in Figure 1. To obtain the various inspiratory times and I:E ratios, the inspiratory rise time % and inspiratory release time % were adjusted as shown in Table 1.

Table 1. Inspiratory rise and release times associated with inspiratory times used in the study. Cycle time was ten seconds and expiratory time was set for four seconds.

	Inspiratory rise time %	Inspiratory release time %
1.33 second IT (1:3)	6.6	6.7
2.0 second IT (1:2)	10	10
4.0 second IT (1:1)	20	20
6.0 second IT (1.5:1)	30	30

The devices were placed in the horizontal position at the inlet of the simulator using 22 mm O.D. and I.D. adaptors (Figure 2). Measurements were taken at the lowest resistance setting and no measurement was taken until the volume reached a steady state (\pm 20 mL of target). After reaching the target volume, the simulator was allowed to run an additional five minutes before recording any data.

Figure 1. Screen capture of complete settings used in the study. Shown: inspiratory time of 4 seconds, expiratory time of 4 seconds, and resulting I:E ratio of 1:1.



Peak inspiratory and peak expiratory flows were measured and recorded from a scrolled reading on the flow-volume loop while mean expiratory pressure was recorded as a digital reading from real time analysis on the ASL 5000. Flow amplitude was measured and recorded from a scrolled reading at 25%, 50%, and 75% of expiratory volume on the flow-volume loop. The values were then averaged to get a mean value. The ratio of peak expiratory flow to peak inspiratory flow was also calculated and recorded. For all parameters, three separate measurements were taken to get a mean value. Statistical analysis was performed using SPSS software (Chicago, IL).

Figure 2. (L to R) Acapella, Aerobika, and vPEP attached to the IngMar ASL 5000 for performance testing

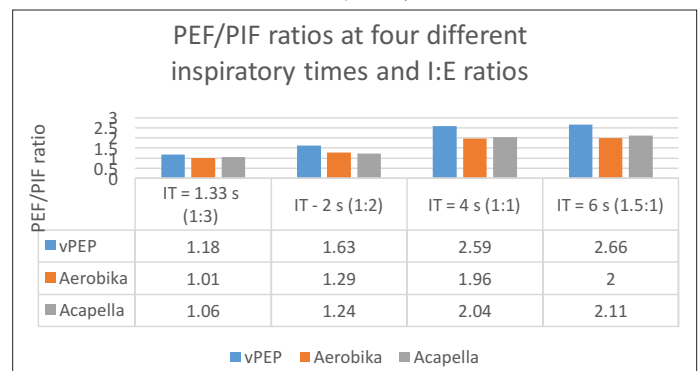


Results

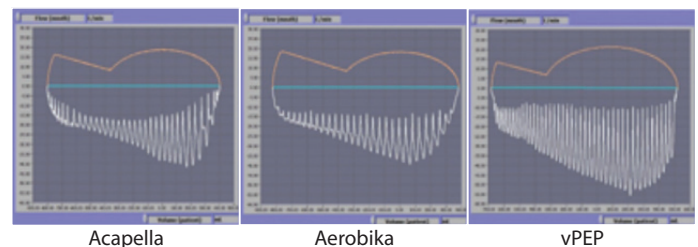
PEF/PIF ratio

In all three devices, as inspiratory time was prolonged, there was an absolute increase in the PEF/PIF ratio ($P < .001$). The greatest mean percentage change in PEF/PIF occurred when inspiratory time was increased from 2 seconds to 4 seconds (58.3% increase) compared to the change from 1.33 to 2.0 seconds (28.7% increase) and the change from 4 to 6 seconds (2.7% increase). There were also statistically significant PEF/PIF ratio differences between all three devices ($P < .001$). The vPEP produced the highest mean PEF/PIF ratio across all four inspiratory times (2.02), followed by the Acapella (1.61) and the Aerobika (1.57). Chart 1 summarizes the PEF/PIF ratios for the

Chart 1. PEF/PIF ratios at different inspiratory times and I:E ratios



Graph 1. Representative flow-volume loops captured at a tidal volume of 1200 ml, inspiratory time 4 seconds, and active expiratory time of 4 seconds.



three devices. Graph 1 shows representative flow-volume loops for the three devices captured at an inspiratory time of 4 seconds and expiratory time of 4 seconds (I:E 1:1).

Absolute value of peak expiratory flow

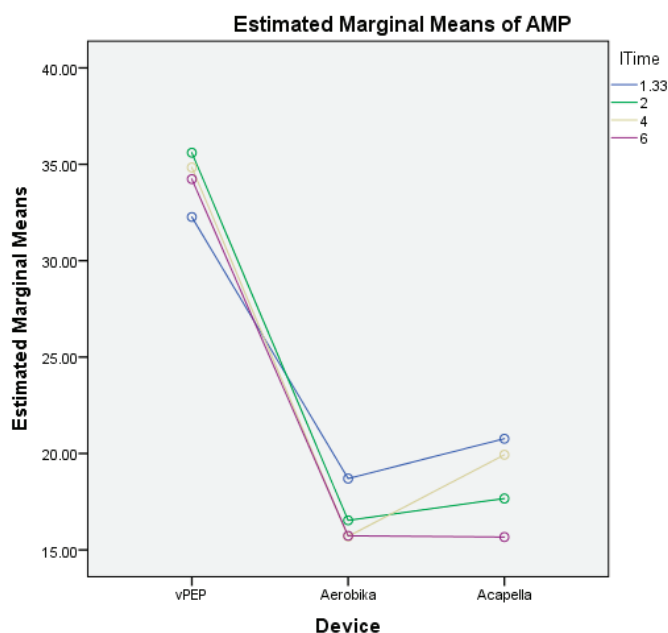
Although the absolute value of PEF differed significantly between the three devices ($P < .001$), it did not vary significantly as the inspiratory time was increased from 1.33 to 6 seconds ($P = .08$). The specific inspiratory and expiratory flowrates for different inspiratory times are shown in Table 2.

Table 2. Peak expiratory and peak inspiratory flowrates at four different inspiratory times

IT	vPEP			Aerobika			Acapella		
	PEF l/m	PIF l/m	PEF/PIF	PEF l/m	PIF l/m	PEF/PIF	PEF l/m	PIF l/m	PEF/PIF
1.33 s	55.6	47	1.18	41.7	41.2	1.01	41.5	39.3	1.06
2.0 s	56.8	34.8	1.63	39.8	30.8	1.29	40	32.3	1.24
4.0 s	56.6	21.9	2.59	38.9	19.9	1.96	42	20.6	2.04
6.0 s	56.3	21.1	2.66	39.6	18.9	2.0	41.2	19.7	2.11

Flow Amplitude

There were significant differences in flow amplitude between the three devices across all four inspiratory times ($P < .001$). These differences can be observed in Graph 1. The range of amplitude was 15.7 – 20.8 L/m for the Acapella, 15.7 – 18.7 L/m for the Aerobika, and 32.3 – 35.6 L/m for the vPEP. Chart 2 summarizes flow amplitude for the three devices.

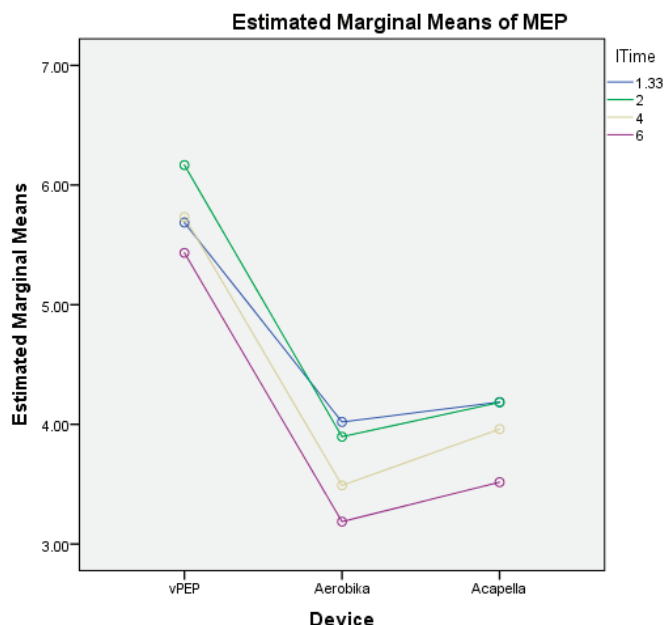
Chart 2. Flow amplitude in liters per minute across four inspiratory times for the vPEP, Aerobika, and Acapella.

Mean Expiratory Pressure

There were significant differences in mean expiratory pressure between the three devices across all four inspiratory times ($P < .001$). The range of mean expiratory pressure was 3.5 – 4.2 cmH₂O for the Acapella, 3.2 – 4.0 cmH₂O for the Aerobika, and 5.4 – 6.2 cmH₂O for the vPEP. Chart 3 summarizes mean expiratory pressure for the three devices.

Discussion

The performance measures in this study — the PEF/PIF ratio, flow amplitude, and mean expiratory pressure — were chosen because collectively these measures represent the primary mechanisms of action for airway clearance devices. The PEF/PIF ratio determines the degree of expiratory flow bias, which is important in driving airway secretions cephalad. The flow amplitude (along with the frequency) determines the quality of oscillations, which would theoretically indicate the degree to which a device reduces the viscosity of mucus. And finally the mean expiratory pressure, which augments the functional residual capacity, is important in moving air behind obstructions through collateral ventilation channels.

Chart 3. Mean expiratory pressure in cmH₂O across four inspiratory times for the vPEP, Aerobika, and Acapella.

Expiratory flow bias is imperative in oscillating PEP therapy and is highlighted as the main finding of the study. As inspiratory time was prolonged, the PEF/PIF ratio and therefore expiratory flow bias improved in all three devices. The greatest increase was seen when the inspiratory time was lengthened from two seconds to four seconds. This is interesting because in the study of 42 healthy volunteers mentioned earlier⁴, the mean inspiratory time during OPEP therapy (excluding the breath hold) was 2.02 seconds, indicating that subjects and presumably patients have a tendency to inspire too quickly.

Continuing on this line, because PEP and OPEP devices sometimes share the same instructions for use, it might be assumed they share the same mechanical characteristics. In actuality, PEP and OPEP devices differ in their ability to produce mean expiratory pressure and expiratory flow bias. PEP devices tend to produce greater resistance, which increases mean expiratory pressure, but decreases peak expiratory flow and therefore expiratory flow bias.

Given these circumstances, instead of focusing exclusively on the pressure created by an OPEP device, an alternative approach might be to put emphasis on the PEF/PIF ratios and the expiratory flow bias they produce. Keep in mind that just as in a cough, it is actually short bursts of increased expiratory air flow that help move secretions up the airway.⁶

Ntoumenopoulos et al, looked at flow bias by comparing peak inspiratory and expiratory flowrates in twenty intubated and

ventilated adult patients.⁷ They found that commonly used ventilator settings produced an inspiratory flow bias in 19 of 20 patients, which would theoretically cause secretion retention. In the same issue, an editorial by Volpe and Amato asks the question, “Is it time to monitor flow bias during mechanical ventilation?”⁸ Their takeaway was that an inspiratory flow bias might be beneficial in conditions such as early ARDS, but also that it might be advantageous to create a “temporary” expiratory flow bias to optimize secretion clearance therapy in paralyzed patients or those with an ineffective cough.

Bennett and colleagues studied the effect of inspiratory time on expiratory flow bias (EFB) generated by manual hyperinflation in a bench model.⁹ They concluded that when using manual hyperinflation to aid in mucus clearance, inspiratory times of at least three seconds for normal compliant lungs and two seconds for less compliant lungs appear necessary to achieve an EFB in their bench model.

Finally, an animal study by Bassi et al also looked at flow bias and mucus clearance.¹⁰ In this study, inspiratory and expiratory flowrates were monitored in eight healthy pigs being mechanically ventilated. Movement of mucus was then assessed fluoroscopically at six different duty cycles or I:E ratios. Radiopaque markers were employed to determine mucus velocity. They concluded that mucus clearance improved with prolongation of the inspiratory time.

Conclusion

The primary hypothesis of the study was supported and found that assuming a constant expiratory time, the PEF/PIF ratio increased as inspiration was prolonged. Specifically, that a slow, four-second inspiration combined with a steady four-second active exhalation (I:E ratio of 1:1) produced a greater PEF/PIF ratio compared to shorter inspiratory times of two seconds or less. With this in mind, it may be time to reevaluate the time-honored 1:3 or 1:4 I:E ratio that is commonly associated with oscillating PEP therapy. The importance of instructing a patient to perform a slow, prolonged inspiration during oscillating PEP therapy cannot be overstated and is integral in order to achieve the greatest possible expiratory flow bias.

The secondary hypothesis was rejected because the study found there were significant differences in the PEF/PIF ratio, absolute value of peak expiratory flow, mean expiratory pressure, and flow amplitude between the three devices as previously outlined. More work is needed in order to determine if these differences affect outcomes in COPD or other patient populations.

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