

HAYEK BCV

Biphasic Cuirass Ventilation

THE IDEAL VENTILATOR SOLUTION



Dr. Zamir Hayek set out to design the ideal ventilator that would be a clinical tool to assist nearly anyone. He achieved his goal with the Hayek RTX ventilator. In doing so, he birthed a new and powerful pulmonary treatment concept, Biphasic Cuirass Ventilation (BCV).

Mechanical assistance of ventilation is frequently provided with an invasive airway and positive pressure breath delivery. Both fraught with significant risk and side effects, these methods of ventilation should be the last resort in meeting the needs of patients. Many patients needing ventilator support can also have their needs met without the

artificial airway for connection to the ventilator and can be supported non-invasively with facial or mask type interfaces. These, although useful, have important limitations. Breath delivery is still positive pressure and patients are frequently intolerant.

Dr. Hayek's invention and creation of his vision of the ideal ventilator resulted in the RTX. The therapies provided with BCV offer significant advantages over positive pressure. This unique device is an important therapeutic tool that can benefit multiple organ systems, particularly in this time when positive pressure appears to be a catalyst for worsening lung disease.

HOW WOULD YOU LIKE TO BE VENTILATED?

Dr. Joseph Cronin M.D.

The best machines or processes are not refined or improved by opposing their core functions. The clever engineer looks to refine and enhance a process by creating conditions that facilitate the core function.

Breathing is a core function of the human-machine. Biphase Cuirass Ventilation facilitates this function. Positive pressure ventilation opposes it. Since they were first marketed in the 1940's positive pressure ventilator monitoring capability and modes of ventilation, have become more varied and complex but have been consistent in their opposition to the normal respiratory cycle of all mammals. Mammals breathe through generating a pressure differential between their thoracic cavity and the surrounding environment. The relative negative pressure within the thorax, created on inspiration, allows the air outside the body to flow to the welcoming alveoli within the lungs residing in the thorax.

The Hayek RTX series ventilator works by facilitating the normal function of the lungs. It delivers this therapy by creating negative and relative positive pressure, via a flexible plastic cushioned cuirass, around the thorax and upper abdomen of the individual in need of respiratory support. It provides this via an efficient pump providing the pressures in a square wave pattern via the cuirass in synchrony with the patient's respiratory demands.

The Hayek RTX series Ventilator assists in this process for people who have either chronic or acute need for respiratory assistance. It does so non-invasively and can assist in easing both inspiratory and expiratory efforts. This device can provide passive support with a continuous negative mode that eases the work of breathing in multiple clinical settings. Additionally, active support can be provided to the patient in synchrony with their efforts while providing a backup rate should apnea occur. Without changing devices, an airway clearance mode can be initiated to provide true chest wall oscillation as well as a cough-assist to clear material from the airways.

The device is used extensively throughout the world in both adult and pediatric populations and for a variety of conditions. A broad demonstration of function was seen in the use of the RTX during the H1N1 pandemic of 2009 as documented by Drs. Ueda and Okada (1). They document the successful use of the continuous negative mode as well as the secretion clearance mode that helped prevent intubations of patients who were experiencing severe hypoxia and distress. They also document the improvement in tidal volume of a 7-year-old patient who required intubation after the application of the RTX. They also emphasized the importance of initiation of therapy with the RTX as early in the disease process as possible to maximize the benefits. This is a task made easier by the nature of the interface of this device as it does not interfere with the patient's ability to eat or communicate verbally. The application of the cuirass also does not interfere greatly with the patient's mobility as it allows them to lie down or sit up in a bed or chair. This improved mobility while still having full ventilator support markedly reduces the risk of compression ulcers and DVT.

We are all aware of the potential for harmful effects when a patient is intubated on a positive pressure ventilator. The impairment of airway clearance and barotrauma that occurs with each episode of intra-tracheal intubation with positive pressure ventilation can be ameliorated with manipulation of settings, but they cannot be eliminated with this mode of ventilation. You can avoid all of these risks with the use of Biphase Cuirass Ventilation administered through the Hayek RTX even in young children with a median age of 15.5 months as Hassinger, A. et al. (2) demonstrated in their nearly four-year study in their PICU. They found a 70% response rate to therapy with the RTX from pediatric respiratory failure of various causes, even in those that failed solo therapy with other non-invasive treatments such as Hi-Flow, nasal RAM, and CPAP.

There are also cardiac function benefits to the use of Biphase Cuirass Ventilation, especially for those with a compromise of cardiac function. As Peng et al. (3) showed in their study, on the continuous negative setting there was an improvement in pulmonary blood flow return and pulmonary vascular resistance for 7/10 of their patients (median age 22); all of whom had some degree of failure of their Fontan circuit. Studies are ongoing in the cardiac population to further quantify the benefit of this intervention and how to optimize the duration and mode of the intervention.

We come back to our original question. How would you like to be ventilated? Certainly, anyone would prefer the method which allows us to continue to eat and remain a verbal and active part in our healthcare decision making. We would all prefer that our airways remain clear and heal without risk of further damage by the intervention being used to help us. We would certainly enjoy the greater mobility and ease of positioning to avoid too much pressure on one area of our body for prolonged periods. The Hayek RTX can ventilate us while attending to all of these issues and, if invasive ventilation is needed, the Hayek RTX can reduce the pressures required to ventilate us and thereby reduce the risk of injury.



CLINICAL BENEFITS

- ✓ BCV improves PaO₂/FiO₂ ratio.
- ✓ BCV increases and restores FRC.
- ✓ BCV supports cardiac function.
- ✓ BCV supports portal, renal, and GI system perfusion.
- ✓ BCV supports better oxygenation and less injury to the lungs.
- ✓ BCV can be combined with HFO₂, NIPPV, PPV and ECMO.
- ✓ BCV doesn't require significant amounts of sedation, if any.
- ✓ BCV facilitates secretion flow from lungs.
- ✓ BCV decreases WOB and caloric expenditure
- ✓ PPV alters function and effectiveness of surfactant, BCV does not.
- ✓ BCV doesn't increase the viral contagion, any more than spontaneous respiration.
- ✓ Increased negative transpulmonary pressure promotes restoration and maintenance of FRC which allows for increased oxygenation and improved compliance.



FDA cleared in US since 2008



- BCV can allow a child who could not eat while on PPV the ability to eat their favorite meal.
- It provides the irreplaceable benefit of allowing a patient to be an active participant in their care.
- BCV can help decrease a grandfather's work of breathing, so they can now have the energy to hug their grandchild.
- BCV allows patients who were once unable to speak with mask ventilation, the ability to tell their spouse or child, "I love you."
- BCV can sustain a patient in their last moments without the use of a mask, so they may say their final goodbyes in comfort and peace.

(1) Ueda (1), K Okada (2) Japanese Society of Pediatric Pulmonology *pediatrics BIPHASIC CUIRASS VENTILATION FOR PANDEMIC A (H1N1) INFLUENZA VIRUS INFECTION IN CHILDREN* Y - kumagaya (Japan) (Japanese Society of Pediatric Pulmonology Pediatrics - moroyama (Japan))
 (2) Nunez, Crystal, Hassinger, Amanda *Critical Care Medicine*. 46(1):561, JAN 2018 Issn Print: 0090-3493 *Respiratory Care*, 2017, Vol.62(12), p.1540(10)
 (3) David M. Peng · Jeffrey D. Zampi · Susan M. Smith · Sunkyoung Yu · Nichole Rottach · Ray Lowery · Heang M. Lim · Lori Q. Riegger · Kurt R. Schumacher · Albert Rocchini, *Hemodynamic Effects of Negative Extrathoracic Pressure in Fontan Physiology*, *Pediatric Cardiology Acute*

CONTACT US TODAY!

The clinical team at Hayek Medical is ready to support all sites with a clinical strategy to provide non-invasive support of breathing in a way that offers the advantages of Dr. Hayek's ideal ventilator.

Patients, while receiving support on BCV can eat, drink, and speak. BCV provides the potential of maximizing the patient's ability to oxygenate without exacerbating the situation with the numerous side effects of positive pressure. Patient's gas exchange can often improve significantly, and more patients can avoid intubation and PPV—all of this with a ventilation intervention that spreads no more virus into the environment than spontaneous respirations.

Please share with any who are seeking a way to head off demand for invasive and damaging positive pressure ventilators or who want to improve the delivery of respiratory care for safety, effectiveness, and comfort. We are ready to assist any site with a training program that will make the implementation of this simple-to-apply intervention smooth and easy.

CLINICAL CONVERSATION

GM: If you could emphasize any aspect or key concept related to optimizing the clinical advantages that BCV brings to the table, what would that be?

JC: Early application of BCV is a key management strategy in handling any acute respiratory event. The maintenance of FRC, dilation of bronchioles, and diffuse alveolar expansion offered by the RTX series device is essential to preventing a cascading progression of dyspnea, hypoxia and airway flow disruption. Whether the process is purely inflammatory or compounded by infection, the maintenance of normal pulmonary air and vascular flow is essential. Without change in physical interface of the device we can switch from solely enhancing the ventilation to a true chest wall oscillating mode with a cough assist mode.

Additionally, the Hayek RTX facilitates this therapy while allowing the patient the potential to eat and vocalize. This allows the individual to continue to participate in their own care. The mobility that is allowed for while using this device will also assist in preventing skin breakdown and peripheral clotting both associated with the immobility that is necessary for more invasive forms of ventilation

GM: Realizing that there are hundreds of citations documenting clinical successes, improved results and that support the concepts of and use of BCV, what

would you say is the strongest evidence for the use of BCV?

JC: The natural heart lung relationship and how other means of support do not enhance the natural respiratory functions and often impair them. As for data, while there are decades of experience with the Hayek RTX. I would say that the recent results of Hassinger et al, mentioned earlier in the document, was profound in that it allowed for the prevention of intubation in nearly 70% of the pediatric ICU patients studied. Additionally, the recent discovery of the benefit to BCV for the population of patients with Fontan circulation by Peng et al will hopefully bring respite to a group whose condition that has been unresponsive to more conventional interventions. This research for the Fontan population continues and we look forward to the insight and knowledge that these investigations will bring.

GM: For the ICU or ED team implementing BCV, what are some ways to maximize success?

JC: Good grounding in basics, advanced super users on each shift, intensivists trained with RT, data collection, celebrate successes and troubleshoot problems with Hayek Clinical Specialists.

GM: The Hayek RTX offers quicker and better results for patients needing support of breathing. It increases

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patient and family satisfaction with care. By decreasing overall length of stay and ICU length of stay, need for mechanical ventilation, decreasing ventilator days, and intensity of illness, it can greatly affect the cost of caring for the complex cardiopulmonary patient, saving systems utilizing BCV many thousands of dollars per case. BCV can be prescribed for home use providing a great tool to incorporate into the home care plan for cardiopulmonary patients at high risk for readmission providing greater discharge flexibility and decreasing readmission frequency. The list goes on, but from amongst these many advantages which do you find the most profound or beneficial?

JC: The clinical benefits manifested by the amplification of natural breathing have been clearly enumerated and to the clinician the ability to avoid barotrauma while improving alveolar and small airway recruitment would be the paramount benefits. While patient will also appreciate this noninvasive relief of their respiratory distress, I think an underappreciated advantage of a chest cuirass is that it doesn't depersonalize a patient like an intra tracheal tube or BiPAP does. We are recognized by our face and, often, our voice. The Hayek RTX ventilator allows the patient to retain more of themselves during therapy.

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Gary
Mefford
RRT

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