Exovent: a new development from old technology

Few contemporary anaesthetists imagining negative pressure ventilation would picture a modern, lightweight, torso-only device, and fewer still would imagine it being described as "extremely pleasant" by a wide-awake subject who was able to eat, drink and talk freely during exhalation (Figure 1). Yet, this is the Exovent experience, as published last month in *Anaesthesia* journal [1]. Unlike its 'iron lung' predecessors, the Exovent can deliver the full features of negative pressure respiratory support on a standard hospital bed. Continuous negative extrathoracic pressure (CNEP) delivers the negative pressure equivalent of CPAP, and negative pressure ventilation (NPV) can be augmented with negative end-expiratory pressure (NEEP), the negative pressure equivalent of PEEP.

From the iron lung to positive pressure ventilation

True collaboration between doctors and engineers is the backbone of medical device development; the first effective iron lung was designed by the Drinker brothers, one a physiologist and the other an engineer. This template was used to treat pneumonia as well as to save tens of thousands of poliomyelitis victims (Figure 2). However, these cumbersome 300 kg, 2 m long devices were largely abandoned when small positive pressure ventilators were introduced in the mid-20th Century. Though it was recognised that positive pressure ventilation (PPV) would reduce cardiac output and require paralysis, sedation, and tracheal intubation, these were considered an acceptable price to pay. Seventy years later, we are increasingly aware of ventilator-associated lung injuries cause by PPV and ventilator-associated pneumonia caused by intubation.

The physiology of NPV

The physics of driving gases down the trachea towards the alveoli through distensible airways produces very different stresses to the lung microstructure and patterns of alveolar expansion compared with gas being drawn into the lungs by the alveolar distension generated by negative pressure. The patchy atelectasis seen with PPV may result from distension of the proximal alveoli compressing the small airways of more distal lung segments. The more evenly distributed forces generated by NPV may explain the rarity of pneumothoraces. In essence, NPV mimics 'natural' breathing more closely.

Applying extrathoracic negative pressure efficiently to healthy humans or animals affects lung volumes and gas exchange in a similar manner to positive pressure. Increasing 'background' inspiratory pressure using CNEP drives similar increases in the functional reserve capacity (FRC) as CPAP, and equivalent NPV and PPV inflation pressures produce similar tidal volumes. However, when animals are ventilated after lung damage from saline lavage or pulmonary artery oleic acid infusion, NPV produces better oxygenation, less atelectasis (Figure 3), less alveolar oedema, and less inflammation than PPV [2]. COVID-19 pneumonia brings the added concern that PPV stimulates the expression of ACE2, the SARS-Cov-2 virus receptor [3].

Positive pressure and negative pressure also have different physiological impacts on the circulation. Raised intrathoracic pressures during CPAP and PPV may cause an ≈ 20% fall in cardiac output by impeding systemic venous return, leading to a smaller ventricular stroke volume. PPV may also have an impact on the pulmonary microcirculation by compressing acinar vessels and shunting blood away from aerated alveoli. CNEP or NPV do not produce detectable haemodynamic sequelae.

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Figure 1. A volunteer in an Exovent

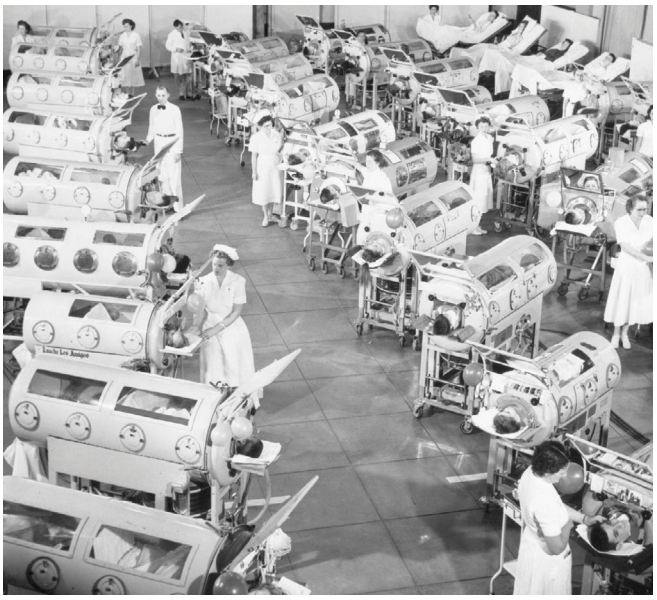

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Figure 2 . Iron lungs in a polio ward

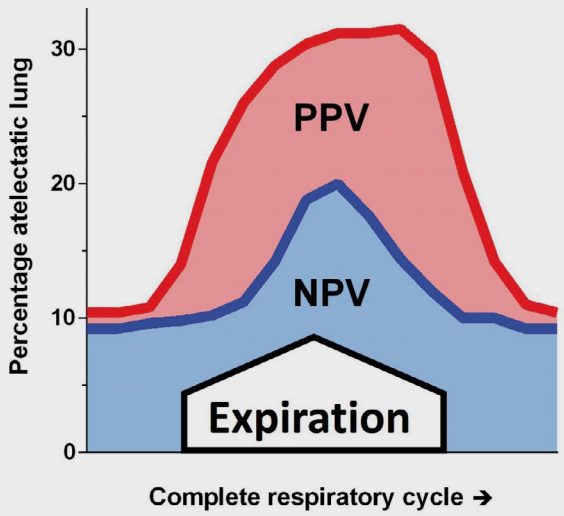

Figure 3. Percentage of atelectatic lung during positive and negative pressure ventilation in surfactant depleted rabbits, adapted from reference [2]

Building a small but effective NPV device

There are four basic NPV designs: whole-body tanks ('iron lungs'); 'wrap' and 'shell' cuirasses; and torso-only tanks such as the Exovent (Figure 4). The efficiency of iron lungs varied between models, but slowly rising inspiratory pressures were difficult to avoid with the then-available suction pumps acting on large tank volumes, limiting their capacity to generate high tidal volumes.

In 'wrap' cuirasses, anorak-type material is laid onto a frame over the patient's torso, and sealed below the axillae and at the hips. Unfortunately, they lose efficiency at low pressures because the material balloons in and out with every breath, and air leaks are difficult to prevent at higher pressures. 'Shell' cuirasses are light and portable, and seal directly onto the anterior chest, abdomen, and lateral rib cage. Applying suction reduces the intrathoracic pressure, but also pulls the shell edges down more firmly, risking restricting diaphragmatic and thoracic wall movement.

The Exovent base with its own internal mattress is placed on a bed, the cover is placed over the torso and arms, and the neoprene neck (hyperboloidal) and hip seals fitted. Its chamber is larger than a cuirass but much smaller than a whole-body tank, which allows the pump to generate almost square inspiratory pressure waves. Members of the Exovent development team (a volunteer group of engineers, doctors and nurses) found it comfortable to use supine at 30° head-up, or prone. It did not produce dyssynchrony so long as the volunteer was instructed to relax and not 'fight it'. Just -5 cmH_2O of CNEP increased the FRC by over 5 $ml.kg^{-1}$, and less than -4 cmH_2O of NPV was sufficient to generate resting tidal volumes of 11.4 $ml.kg^{-1}$ (Figure 5). This compares with typical chamber pressures of -20 to -40 cmH_2O for most previously-reported NPV devices.

What clinical contributions could Exovent make?

The Exovent allows healthy adults to receive the negative pressure equivalents of CPAP, and ventilation plus PEEP, comfortably. The enclosure can be removed quickly by two people if needed, and the window and self-sealing portholes allow for clinical monitoring and undertaking procedures. Despite fears to the contrary, users have not found the chamber claustrophobic. This may be because they can move relatively freely inside and can easily breach the seals with their hands, either producing a momentary pressure drop or releasing the vacuum completely.

We have not yet trialled the Exovent in patients, but this is planned. However, the extensive history of NPV suggests that it may provide a useful tool alongside conventional therapies in treating people with COPD, pneumonia including COVID 19, and neuromuscular weakness. In particular, we wonder if a key advantage may be the ability to move patients seamlessly between CNEP and NPV without the need for tracheal intubation, as even relatively high extrathoracic pressures remain comfortable. This contrasts with the intolerance of pressures sometimes required for CPAP or conventional non-invasive ventilation, which may then require tracheal intubation. This may offer a benefit to patients with a ceiling of treatment.

Finally, there are resource considerations. A UK version is anticipated to cost approximately £8000, considerably cheaper than conventional positive pressure devices, and we aim to produce a low-cost version for low and middle income countries for less than £500. It also has the potential to reduce oxygen usage as it is powered by electricity (potentially including batteries), so patients will only need facemask or nasal oxygen. It is an ambition of the Exovent charity (1189967) to improve access to negative pressure ventilation globally.

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3. Huang S, Kaipainen A, Strasser M, et al. Mechanical ventilation stimulates expression of the SARS-Cov-2 receptor ACE2 in the lung and may trigger a vicious cycle. Preprints 2020; doi:10.20944/preprints202005.0429.v1.

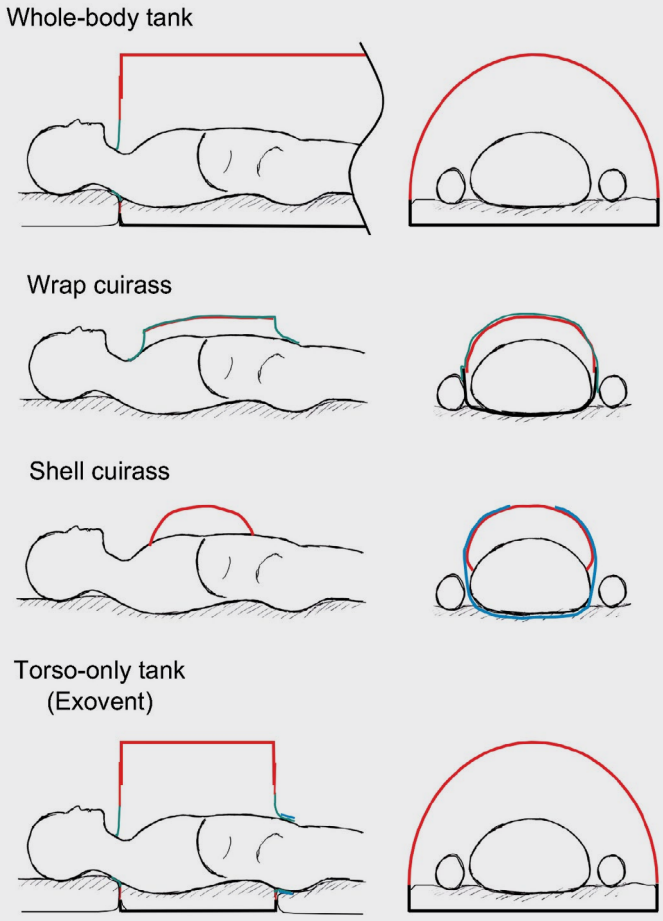

Figure 4. Types of negative pressure ventilator chambers. Red - rigid material; green – cloth or flexible material; blue - velcro band

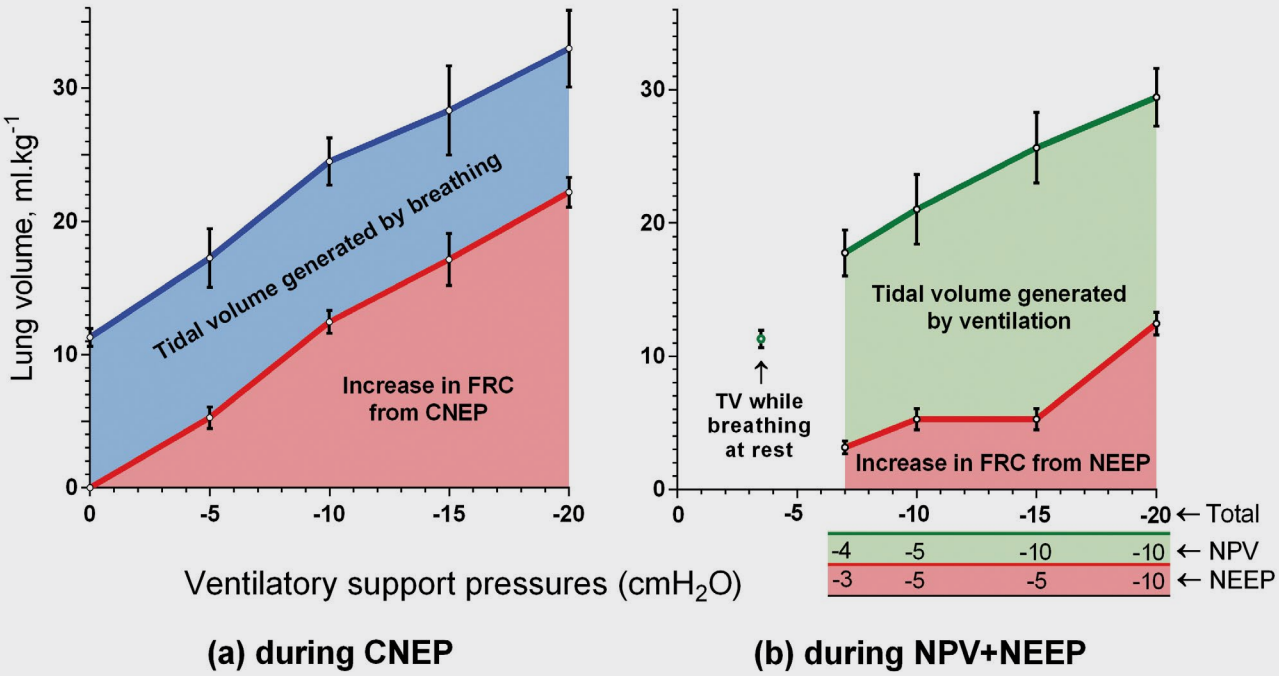

Figure 5.Tidal volumes during NPV and NEEP, and increases in FRC during CNEP generated by the Exovent in six healthy volunteers, from reference [1]. Error bars = 1 SD

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