Infant Flow SiPAP
A Novel Non-Invasive Respiratory Support System for Newborns:
Background for its Application

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For sick babies, the early hours of life are usually characterized by the need for respiratory or circulatory support. Premature babies are especially likely to have respiratory problems because their lungs have not had enough time to develop before birth. Such respiratory problems can include decreased pulmonary compliance, decreased functional residual capacity (FRC) and airway closure.\textsuperscript{1,2} Treatment of newborns requiring respiratory support is typically done in an intensive care environment.

Historically, in many countries, the initial treatment method prescribed for infants with respiratory problems is intubation and mechanical ventilation. Intubation involves placing a tube into the newborn’s tracheal airway. Mechanical ventilation is a process that achieves a positive inflation of the lungs via the tube, thereby permitting gas to be exchanged in the lungs. For many years now, this treatment method has been followed by the use of a therapy called CPAP (continuous positive airway pressure) as a transition or weaning technique from mechanical ventilation to total independent breathing.\textsuperscript{3,7} CPAP is a technique that applies a counterbalancing force of air pressure to the normal recoil of the lungs that would cause the alveoli to collapse. The purpose of the application of CPAP is to maintain a normal lung volume in an infant while allowing them to breathe on their own. It is also known to use CPAP as an initial treatment for babies with respiratory problems before resorting to intubation and mechanical ventilation.\textsuperscript{4}

CPAP utilizes slight positive pressure during the respiratory cycle in a spontaneously breathing baby to increase the volume of inspired air and to decrease the work and effort of breathing. This treatment can be applied by mouth, nose, or through ventilation tubes. Nasal CPAP is administered through nasal prongs that are placed and secured in the infant’s nose. Again, a small consistent positive pressure is used to increase the amount of air inhaled without increasing the work of breathing.

Since most newborns are preferential nose breathers, nasal prongs constitute a simple vehicle for the application of CPAP by non-invasive means. Such nasal administered
CPAP is referred to as NCPAP. One significant problem with early NCPAP equipment was the combination of high resistance to the breathing flow through the prongs and less effective pressure generators. This combination resulted in airway pressure instability that increased the work required for an infant to breathe, an undesirable condition. The unstable airway pressure also results in a less effective treatment in relation to the recruitment of alveoli and increasing lung capacity.

Although NCPAP has been shown to provide significant benefits to newborns, and has been associated with a lower incidence in chronic lung disease when compared with conventional ventilation, approximately half of all premature infants treated with this modality, fail to be able to be maintained on this therapy alone and require endotracheal intubation and mechanical ventilation. Failure of nCPAP either during escalation of respiratory support towards intubation and mechanical ventilation, or during de-escalation of respiratory support during weaning from mechanical ventilations, is usually attributed to several factors. In a recent large study of nCPAP in premature infants, the top three causes of failure were attributable to:

1. Respiratory center immaturity resulting in bradycardia or apnea (58%)
2. Hypoxia most likely resulting from alveolar instability (16%)
3. Hypoventilation resulting from fatigue (15%)

This failure rate suggests that additional technology may be required if remaining benefits are to be realized. In particular, the application of SiPAP, which involves an improved NCPAP system, provides intermittent sighs or deep breaths during CPAP administration. It is believed that injecting sighs into administered CPAP will have several benefits, including, stimulating the respiratory center, stimulating the release of surfactant, recruiting alveoli, and offloading respiratory work. These effects may reduce the need for reintubation and mechanical ventilation, and provide the benefit of reducing the incidence of CLD that is statistically associated with mechanical ventilation.

The purpose of the SiPAP nasal CPAP system is to deliver intermittent sighs to infants on this nasal CPAP system. The system is an adjunct to a standard fluidic CPAP
system. It has the capability to set a second higher level of CPAP pressure for a variable time period and at a variable rate. This second pressure level generates the equivalent of a sigh for the infant.

The functional controls of the module control the “on” and “off” time of an additional gas flow up to 5 LPM. The system has a gas supply that is delivered by an electronic solenoid, which is controlled by a microprocessor. The gas is delivered into the CPAP circuit prior to the humidifier. The module has a control for the manual setting of the additional flow. This additional flow is displayed on the display of the CPAP system and is increased with the flow control until the sigh pressure level desired is indicated on the CPAP system display. The settings for inspiratory time and frequency are adjusted on the LCD display. These controls enable the setting of the second CPAP pressure, the duration of the higher pressure and the time between the cycles.

Typically the higher pressure is set 2-3 cmH2O above the baseline CPAP pressure. Data from Pandit, et al., suggests that a pressure of approximately 2 cmH2O will increase the lung volume by 4-6 ml/kg in infants recovering from RDS or with mild RDS (i.e., with reasonably normal compliance).8,9 With each sigh period, the gas added to the circuit causes a slow rise in CPAP pressure to the higher level. This time period is a function of the added flowrate and the volume of the humidifier chamber. Our experience with Fisher & Paykel chambers would indicate that there is a <1 second rise time. This would mean that the infant would be breathing throughout the rise and fall time of the sigh. Synchronization is not part of the design and the rise and fall of pressure is by intention to be slow and not a breath that an infant would fight. Limited case series experience with the system in newborns in Europe suggests that they seem to rapidly adjust to the changing levels of CPAP without distress, while finding clinical benefits of reduced extubation failures and need for respiratory stimulants.10,11

When considering why neonatologists are hesitant to extubate infants from mechanical ventilators, thoughts were on central apnea and very small infants who fatigue due to inadequate chest wall mass. The development of this system was therefore directed at
these two patient populations. First of the patient populations was infants with central
apnea who just require a sigh to stimulate their respiratory center. For these infants, a
slow sigh rate would probably be sufficient. The second population is smaller
premature infants who tire from respiratory work. For these infants, more frequent sighs
would reduce the work of breathing that they carry and may further reduce the incidence
of need for reintubation. As they grow and develop stronger respiratory muscles, the
sigh rate can be reduced.

As previously described, the rise time is too slow to directly synchronize the shift in
CPAP pressure with respiratory effort and therefore questions of the infant breathing out
of synchrony with the CPAP system and work of breathing are brought to mind. One of
the unique aspects of the fluidic CPAP system is that as long as the airway pressure is
equal to or greater than the set pressure, the gas flows away from the infant. This
means that when the higher pressure is raising lung volume, the pressure that the infant
breathes against is no higher than the set CPAP pressure and there are not pressure
swings during the respiratory cycle. This is a very low work of breathing shift in lung
volume as the infant is not breathing out against an inrushing flow and both the baseline
and sigh pressures are within the range of clinically applied CPAP. It can equally be
argued that the upper sigh pressure is the clinical level with intermittent reductions in
pressure.

As previously described, the FDA 510(k) approved SiPAP unit is built upon a well
studied CPAP system. There are no differences in the patient interface between the
SiPAP and CPAP system. The only difference is the addition of intermittent gas flow to
the breathing circuit. In the event of a failure of the SiPAP section of the system, the
patient will remain on the standard CPAP section of the system.

The pressures used by the SiPAP system are typically set with maximum pressure of 6-
9 cmH₂O, however they are limited to a maximum of 11 cmH₂O of total pressure (CPAP
plus SiPAP). These pressures are at or below the pressures used for mechanical
ventilation of newborns. The SiPAP system retains the internal monitoring and safety
systems of the CPAP system that includes alarming if the SiPAP pressure exceeds the baseline pressure by more than 3 cmH2O and a safety valve that dumps all gas flow if the pressure exceeds 11 cmH2O.

References:


