The Innovation of Primary Head Protection for Infection Prevention

The Problems of PPE for Primary Head Protection

A protective head covering is needed in healthcare workers' daily tasks, such as treating infected patients, performing surgery procedures, reprocessing devices, cleaning up, gathering contaminated bed sheets or apparel and handling biomedical waste. However, conventional disposable head coverings do not always provide adequate coverage and unrestricted head movement.

Primary Head Protection was the critical missing component in conventional PPE. This was because there was no material available for making a protective hood that could be form-fit to the contours of the wearer's head and face.

Materials for Making Disposable Protective Hoods

Personal Protective Equipment (PPE) is worn to minimize exposure to harmful substances and reduce workplace injuries and illnesses. Disposable protective hoods are commonly made of plastic film laminates, Tyvek sheets or nonwoven fabrics for their barrier functionality and low cost.

1. Plastic Films are the best material in shielding against corrosive chemicals and organic solvents with their chemical inertness and absolute imperviousness to liquids. The film laminates on textile are to obtain high strength against tearing and puncturing. They are used for making hazmat suits. Laminates with nonwoven backing, having low strength against tearing and puncturing, are used for disposable protective apparel.

   The protective hoods made of film laminates are impervious to air, so they have to be equipped with an air-fed system. They are bulky, inconvenient and expensive for many daily jobs.

2. Tyvek Sheets, like plastic film laminates, are impervious to liquids and chemically inert. They are used to make light-duty hazmat suits because their protection against puncture or abrasion is limited. Tyvek sheets are called "breathable material" by having a moisture vapor transmission rate (MVTR) of 5-10 liters/m²/24 hours tested at 100F°. However, the term "Breathable" used to describe their structure can be misleading. Such low volume of transmittable air is not adequate for human breathing since the average human respiratory rate requires at least 5 liters/minute.

   Tyvek hoods are unbearably hot to wear. Without being equipped with an air-fed system, it can cause uncomfortable anxiety, dizziness, and exhaustion from the buildup of heat and humidity. The design of exposing the wearer's face is most likely to avoid suffocation accidents.

3. Nonwoven Fabrics are the best material for achieving a balance between "breathability" and "barrier functionality". Their dense fiber-composite structures have ultrafine intertexture openings for air to flow through while maintaining particle filtration quality.

   Spunmelt nonwovens made of polypropylene (PP) fibers are popularly used for making face masks, surgical gowns and coverall suits. A common problem of spunmelt nonwovens is their stiffness.

When making nonwoven hoods barrier functional, the high basis weight material is too stiff to fit well even when incorporated with elastic components. Consequently, nonwoven hoods are not popular.

4. VitaFlex's Latex-free Elastic Nonwoven Fabrics are the breakthrough material that gives a soft and stretchy structure while maintaining the breathability and barrier functionality of nonwovens. This enables the making of protective hoods that are soft and stretchy to fit comfortably and securely on the wearer's head.

   By combining different types of elastic nonwovens in a multi-layer structure, soft-stretch hoods have been created with specific functionality such as blocking micron-sized particles (asbestos, silica, and glass fibers), bacteria, paint overspray, fluid or blood splashes, and UV rays. They also provide a physical barrier against scratches.

The Development of Soft-stretch Hoods for Primary Head Protection

The poor uniformity of nonwovens is a major problem which can be visually observed by the many sparse spots on the fabric, especially for basis weight below 20 gram/m^2 (0.62 oz/yd^2). We source our precursor nonwovens from advanced manufacturing lines having multiple spinning stations that can create a multiple layer composite structure to improve uniformity. **Triple-layer quilted construction** of our hoods further enhances their uniformity, achieving mass distribution with standard deviation of <5%.

Nonwovens' static surface constantly attracts particles from the air. There is serious concern with conventional nonwoven apparel and drapes regarding contamination from many hours of exposure during the manufacturing process involving manual cut-and-saw and assembling. On the contrary, the manufacturing and packing of our soft-stretch hoods are done in the same room and completed within 4 minutes. Throughout the manufacturing process, our hoods remain on bench top 27" above the floor and are not touched by bare hands. The chance of contamination is greatly reduced.

Keeping heads cool was a major criterion when we developed the soft-stretch hoods to be worn for extended periods of time. Throughout the development process, the FDA guiding principles for surgical masks were followed. An indicator of breathability is to measure the differential pressure (ΔP, mm H_2O/cm^2) across the web structure according to test method MIL-M-36954C. FDA guidance on surgical masks states that the wearer will feel hot when wearing a mask having a ΔP of more than 5. The ΔP of the soft-stretch hoods' structures is constructed to be less than 3, so the wearer can breathe normally. The wearer should feel cool and comfortable in extended wearing due to the low ΔP of the hood's structure allowing perspiration vapor to escape through it. There is no unbearable heat or humidity build up inside the hood.

Wearing a face mask (by general public as well as patients) was found effective in bringing the SARS outbreak under control. Airborne transmission of Ebola from an infected passenger in air travel didn't happen. Those facts seemed to indicate the long-distance air transmission rarely carries a critical mass capable of triggering an infection unless in the future a super infectious disease is encountered. Meanwhile, **contact transmission is the most common threat** from many communicable diseases. Infectious substances can fall on the healthcare worker's hair and skin, and infection occurs when they touch such contaminants or other contaminated surfaces and subsequently touch their nose or mouth. **The best practice for preventing contact transmission is to keep the head and neck fully covered all the time.**

A breathable filter for absolutely blocking a 0.05 µm virus does not exist. But we don't need it. A virus does not fly and maneuver like a mosquito to attack people. Instead, viruses are carried by airborne particles and spit, body fluid, or blood, which attach to surfaces they contact. Individual viruses do not have the ability to migrate through even a thin surface. We only need to block their carrier from reaching the facial mucous membranes.

Healthcare workers' heads are always at a higher position above their work subjects and at a distance. To qualify the hoods' structures for splash resistance, ASTM Method 1862 was used. Synthetic blood was sprayed onto the surface of hood at a distance of one foot, at three different velocities corresponding to a human blood pressure of 10.6, 16.0 and 21.3 kPa (80, 120 and 160 mm Hg).

In considering the reality that healthcare workers never put their head or face tightly against a pot of pressurized blood or body fluid, ASTM F1670/1671 tests were not used. There is no benefit in sacrificing the comfort and coolness of protective head covers by coating or laminating them with an extra layer of polymeric film to have the imperviousness against pressurized synthetic blood (of 2 psi) for up to 1 minute and then maintain the contact for another 54 minutes at atmospheric pressure.

The ASTM F2299 Particle Filtration Efficiency (PFE) and ASTM F2101 Bacteria Filtration Efficiency (BFE) tests were used to examine the properties of the hoods' structures. The tests were conducted at an air flow of 28.3 liters/minute to evaluate particle retention of latex particles of 1 µm and aerosols of 3 µm carrying Staphylococcus aureus. **Since the hoods fit tightly against the wearer's hair and skin, no air flows through them, so airborne particles rarely penetrate through to the wearer**.

For Infection Prevention, Two Grades Are Available

Soft-stretch Hairnet and Biosafety Hood

Low-cost effective barrier can be conveniently and comfortably worn in conjunction with existing PPE to give full-head protection

The Soft-stretch Hairnet is a **hygienic barrier** made of special grade latex-free elastic spunmelt composite with ultra-fine fibers and supremely uniform web formation.

- **Shields against low concentration airborne particles and droplets**
- **Prevents contaminated hands from touching facial mucous membranes**

Tested by spreading a 1 mm layer (100 mg/cm²) of talcum powder on its surface, 76% showed no leakage at all. And, no more than 0.2 mg/cm² leaked through the structure on the rest of the samples. Therefore, this material is considered capable of blocking low contraction airborne particles.

When subjected to the **hydrostatic pressure test**, the structure withstood a column of water 14 cm tall. Tested by spraying mist from two feet, while a few mm-sized droplets penetrated the structure, it effectively blocked fine droplets.

The max-cover design maximizes the coverage of the wearer's scalp, face and neck. It can be expanded up to 27" circumference. **For a small head**, a head band can be worn under the hood to give a tighter fit.

When in a potentially hazardous environment and wearing a full protective suit is not applicable, medical professionals now have better protection by wearing the soft-stretch hairnet over a technical mask and under a face shield.

Caution: VitaFlex's soft-stretch hairnet is not a substitute for more effective prevention methods and its use should be considered only when other means of protection are not feasible. While it provides a protective layer against contaminates, there is no guarantee of absolute blocking effectiveness to all airborne particles and droplets.

VitaFlex's Biosafety Hoods

- **Critical protection in responding to epidemic outbreaks and treating infected patients.**
- **Prevent contact transmission in many daily jobs such as performing surgery procedures, reprocessing devices, cleaning contaminated rooms and furniture, bundling dirty bedding, and handling biomedical waste.**

The triple-layer structure of Biosafety hoods achieves superior barrier functionality while keeping the wearer's head cool during extended use.

- ΔP <3 mm H_2O/cm^2. (MIL-M-36954C)
- Particle filtration efficiency (PFE) >90% against >1μm particles. (ASTM F2299); Bacteria filtration efficiency (BFE) >90% (ASTM F2101)
- Qualified as a level 1 fluid barrier (ASTM F1862) with resistance to synthetic blood penetration at 80 mmHg sprayed from a distance of 12".

Practical Solutions for The Problems of Conventional PPE

1. **The Disposable N-95 Masks** are commonly used by healthcare workers for respiratory protection. However, N-95 masks do not fit well on many people due to varied face shapes. Their latex straps are either too loose or too tight for proper fit. Also, fit testing cannot always guarantee against leakage since the mask can move while working. In reality, a protective hood is also needed to block the airborne droplets expelled at high velocity from a patient's coughing and sneezing that spray on the face and neck or fall on the hair. Those contaminants pose an equal or greater infection risk from subsequent contact transmission.

Biosafety hood can be comfortably worn with a mask or respirator to keep the entire head, face and neck protected. Many workers have confirmed our internal tests that wearing our hood under a mask (photo on the left) provides an additional layer of barrier and reduces gapping.

Fit test respirator as always with our Biosafety hood to confirm its seal. If the hood interferes with the fit, try wearing it over the mask (photo on the right).

2. **The Hooded Coveralls** have been criticized for severely restricting the wearer's head movement and mobility. While working, the coverall hood easily pulls away from the wearer's face. Usually, duct tape has to be used to attached it to the face shield of a respirator. This actually worsens the problem of restricting head movement.

The updated guidance of the CDC recommends the use of coveralls without integrated hoods. **It is practical and economical to wear our Biosafety hood with an un-hooded coverall suit.** Wearing Two Hoods is recommended. That way, after being in a contaminated situation, the outer layer can be removed with the respirator leaving the inner layer in place protecting the head until all contaminants are cleaned away.

3. **Powered Air Purification Respirator (PAPR)** provides complete coverage for the head. However, of great concern is that the removal of the PAPR hood would immediately expose the wearer's head to contaminants accumulated on the suit. Even changing the doffing procedure to remove the PAPR last leaves a risk of accidental self-contamination from the contaminated PAPR.

Our Biosafety hoods should be the first PPE put on and the last removed. Wearing a Biosafety hood under the PAPR hood keeps the head protected from contact transmission when removing the remaining protective apparel.

Caution: VitaFlex's soft-stretch hoods are NOT for replacing mask in OSHA requirements. Not for blocking concentrate detergents, high viscosity solutions, organic solvent, toxic or bio-hazard gases, fumes, or vapors. Not for blocking pressurized liquid and particles.