



Development and characterization of triclosan coated heat and moisture exchange filter for ventilation therapy

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An indigenous heat and moisture exchange filter has been developed using an open cell reticulated hygroscopic impregnated polyurethane foam and polypropylene nonwoven to maintain heat and moisture exchange and bacterial filtration efficiency respectively. Also, the spun bond polypropylene nonwoven is treated with an optimized concentration of biocide (triclosan-5gpl) mainly on the 1st contact layer of ventilator gas using padding mangle in 2 dips/2 nips method for better antibacterial efficiency. Three different polypropylene made nonwoven materials [spunbond (SB), meltblown (MB) and needle-punched (NP)] are stacked in different layer arrangement and evaluated for their efficiency in filtering bacteria. The five-layered composite filter (SB-MB-NP-MB-SB biocide treated) with double layers of meltblown and spunbond treated with biocide, in addition to the needle-punched middle layer, shows a bacterial filtration of 99.9% along with excellent antimicrobial properties and acceptable pressure drop. The developed biocide-coated multilayer composite filter provides comfortable and ideal humidification to the users besides delivering excellent antimicrobial activity. This developed filter will be an alternative to existing commercial filters, without any compromise, and having all the inherent properties.

Keywords: Bacterial filtration efficiency, Biocide, Heat exchange filter, Moisture exchange filter, Nonwoven fabric, Open cell reticulated polyurethane foam, Pressure drop

1 Introduction

During mechanical ventilation in intensive care or under anesthesia, with an endotracheal tube (ETT) in place, the air conditioning functions like humidification, warming and filtration functions of the nose and the upper airways are bypassed¹. The gas delivered from a mechanical ventilator at room temperature with an insignificant water content create some damage to valves and regulators in the distribution network, worsening the situation². This leads to airway damage (destruction of the cilia and mucous glands), subsequent altered pulmonary function (fall in functional residual capacity) and heat loss (drop in body core temperature)³.

The inhaled gas before reaching the lungs through the trachea must be adequately humidified with proper temperature; which is usually carried out with the help of an external element. So far, these objectives have been performed by water bath humidifiers³. This water bath humidifier comes under an active humidification process, wherein heat energy is supplied to the gas to ensure its moisture content. The control of this energy is important, as over-

humidification and heating may cause water intoxication, water clogging and airway burns².

The other device, the heat and moisture exchanger filter (HMEF), which passively retains the heat and humidity combined with the bacterial filtration, acts as a barrier to the passage of bacteria.² The so-called passive humidifier functions by retaining the moisture in the exhaled air. Thus, this device does not have any of the disadvantages².

The basic components of heat and moisture exchangers (HMEF) are foam, paper, or a substance that acts both as a condensation and absorption surface. The material is often impregnated with hygroscopic salts, such as calcium chloride, to enhance water retaining capacity¹. Calcium chloride (a hygroscopic agent) attracts moisture from the air and can be regenerated at low temperatures of 40 °C. With the increase in the moisture content of the air, the level of moisture absorbed by the heat and moisture exchanging element will be high. If the humidity of the air increases, more moisture is absorbed by the hygroscopic element. If it decreases, water evaporates from the hygroscopic element into the air⁴.

A comparative study between Bennett Cascade 2-a vaporizing humidifier and a hygroscopic HME-DAR

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hygroster was conducted². Inpatients were evaluated for the ability to preserve heat and humidity with a minute ventilation >10L/min, for a 24h period. The performance of the Bennett cascade was found equivalent to a vaporizing humidifier, that could retain heat and moisture for 24 h.

The most frequently used filter media in HME consists of nonwovens or their composites. The efficiency of the filter media depends on the way it is constructed. Influencing parameters are the nature of fibre, its tailorability and the way it is manufactured⁴. In normal working conditions, it can reach a relative humidity of 70%; however, to attain its best level of efficiency, it will take more than 20 min. The size of the heat and moisture exchanging filter is big and has to be placed very close to the patient during use to reduce the inclusion of dead space. Due to higher minute volumes (>10 L/min), their function seems to be very poor. Due to smaller tidal volumes, it may be responsible for considerable dead space, which is impossible to use; during the critical care stage. When the temperature difference across the membranes is higher, the exchange of heat and moisture within the filter will also be higher⁵.

Hospital-acquired pneumonia remains one of the main causes of infection in the intensive care unit (ICU) and is associated with the length of hospital stay, duration of mechanical ventilation and use of a broad spectrum of antibiotics. This condition results in increased hospital costs and patient mortality. While being continuously exposed to the mechanical ventilator for a longer duration, approximately 48-72 h, the rate of being affected with this pneumonia is reported to be high. Mortality due to ventilator-associated pneumonia (VAP) varies between 24% and 50%, reaching 76% in high-risk situations⁵. This suggested that both heated humidifiers and HME can be utilized in the ICU, without any significant impact on ventilator-associated pneumonia incidence. Concerning the cost incurred with the active humidifier and associated disadvantages, the passive humidifier HMEF seems to be a better alternative for mechanically ventilated patients.

Among the various micro-biocides, phenol compounds are of particular importance, especially a compound from the group of bisphenol micro-biocides (2,2,4'-trichloro-2'-hydroxydiphenyl ether - triclosan)⁶. This has been used for years in medicine and stomatology as a disinfectant and antiseptic agent⁷. The added material strongly restricts the growth of microbes. The advantage of using triclosan as a biocide is its low minimum inhibitory concentration (MIC), which reduces the side effects accompanying the use of each biocide⁸.

Antibacterial agents like silver and copper oxide will usually be treated with filter layers to promote antibacterial activity⁹. In this study, to the best of our knowledge, triclosan has been used for the first time to explore the developed filter for antibacterial activity along with hygroscopic foam for acting as an HMEF.

2 Materials and Methods

2.1 Hygroscopic Material

Open-cell reticulated polyester-based hygroscopic polyurethane foam was purchased from M/s High Specification Products, UK. The specifications for the purchased foams are given in Table 1. Triclosan was purchased from Sigma Aldrich, USA, and used without any further modification.

2.1.1 Physical Characterization of Hygroscopic Material

The sourced foams were characterized for hygroscopicity to determine the add-on weight in grams and pressure drop in kPa at 60 LPM.

2.1.1.1 Determination of Hygroscopicity of Hygroscopic Foam

The add-on weight in grams was assessed as per the procedure described in ASTM E 96-95 for "Hygroscopicity" (SDL Atlas, Model: M259B, Hong Kong, 2009). Here, the tendency of plastic foam material to absorb moisture, while the moisture vapor is getting transmitted through it for 24 h, is calculated as add-on weight, based on the difference in weight between the dry weight and the wet weight of the plastic foam sample. There are 6 test procedures available in ASTM E 96, and we have chosen upright cup method- procedure B which is opt for this study.

Table 1 — Foam specifications

Parameter	Foam 1	Foam 2	Foam 3	Foam with commercialized HME filter
Type of material		Reticulated polyester-based hygroscopic polyurethane foam		
Mean flow pore diameter, micron	74.36	76.85	88.50	64.68
Thickness, mm	12.50	12.65	12.43	13.50

As per ASTM E96 Procedure B, the test was carried out in water method at 23 °C temperature and 50% RH for 24 h. Water is taken in the standard test container and its opening portion is covered with sample. Then the container is weighed. After 24 hrs, the container is reweighed. The difference between the test results are used to calculate the water vapour transmission rate (WVTR) through the sample.

2.1.1.2 Determination of Pressure Drop of Hygroscopic Foam

The pressure drop was measured with the help of a TSI instrument as per the standard ISO 9360-1: 2009 (TSI, Model: SKU 4080, USA). The difference in the pressure level that exists, when a continuous flow of gas is given with a foam material with the inlet and outlet of the foam device and for the gas stream flowing across it, enables us to calculate the pressure drop of the foam material. The pressure drop was evaluated with the foam materials due to the hygroscopic agent coated over its surface; how it goes to influence the passage of air through the surface.

2.2 Filters

Two different varieties of nonwoven materials, such as spunbond and melt blown, were purchased from M/s Alpha Foams, India. In addition to that, SITRA-developed double sided needle-punched nonwoven fabric was also used.

The thickness of the purchased polypropylene made spunbond nonwoven fabric and melt blown nonwoven fabrics were found to be 0.20mm and 0.12mm respectively, whereas the peeled off layers from the commercially available composite filter consists of four spunbond nonwoven fabric layers each having 0.17mm thickness.

Using 2.5 denier, 51mm length polypropylene fibre, needle-punched nonwoven fabric was developed which was similar to that used in commercially available composite filter.

2.2.1 Physical Characterization of Filter Material

The sourced and developed filter materials such as spunbond, meltblown and needle-punched materials were characterized for weight per square meter, combined mean flow pore diameter and pressure drop, towards ensuring the filtration efficiency and physical parameters.

The weight per square meter of the nonwoven fabric material was evaluated as per ISO 9073-1:2015. The influence of weight per unit area concerning the filtration mechanism and the nature of capturing the sub-micron particulate matter were studied.

Porosity is a critical factor that describes the permeability of filter fabrics. The mean flow pore diameter was evaluated with the Porometer, PMI-made and Model: CFP-1200A, capable of measuring pore size between 0 micron and 500 micron. The influence of the mean flow pore diameter of the filter layers on the passage of bacteria during the continuous gas flow was evaluated. The pressure drop was measured as per ISO 9360-1: 2009 standard.

2.3 Preparation and Morphological Analysis of Antimicrobial Filter

Out of the sourced and developed filter materials, such as spunbond (SB), meltblown (MB) and needle-punched (NP) fabrics, spunbond material was padded (2 dips/2 nips padding mangle) with the 5% biocide (triclosan) and dried at 40°C, to enhance its antimicrobial activity, without compromising the bacterial filtration efficiency⁶. The untreated and treated materials were characterized in field emission scanning electron microscope for their change in surface morphology, towards evaluating the influence of biocide treatment on the pore size of the filters.

2.4 Development of Composite Filter

Five different composite filter fabrics were prepared in which the individual layers were arranged as given below to identify the combination suitable for developing HME filters:

- (i) Three-layered nonwoven fabrics
SB-NP-SB
- (ii) Four-layered nonwoven fabrics without meltblown
SB-NP-SB-SB
- (iii) Five-layered nonwoven fabrics without meltblown
SB-SB-NP-SB-SB
- (iv) Four layered nonwoven fabrics with melt blown
SB-NP-MB-SB
- (v) Five layered nonwoven fabrics with melt blown
SB-MB-NP-MB-SB

With all the layered nonwoven composite fabrics, triclosan-treated spunbond nonwoven materials were used as bottom layers, and this layer represents filter layer which gets 1st contact with the oxygen during ventilation. Needle-punched nonwoven fabric was used as a middle layer. Further, meltblown nonwoven fabric was used as 2nd and 4th layers in 5-layered composite fabric (with meltblown) and as a 2nd layer in 4-layered composite fabric (with meltblown).

2.5 Assessment of Antibacterial Activity

2.5.1 Parallel Streak Method

The antibacterial activity of the triclosan padded filter layer was studied as per AATCC 147-2016 test method. Briefly, an inoculum of *S. aureus* ATCC 6538 and *K. pneumoniae* ATCC 4352 was prepared by transferring 1.0 mL of 24 h broth culture into 9.0 ml of sterile distilled water. A loopful of inoculum, after mixing was transferred to the surface of the sterile agar plates by making 5 parallel streaks of 6 cm length, spaced 1 cm evenly apart without refilling the loop, covering the central area of the nutrient agar plates. Triclosan padded filter layers of 25 × 50 mm were transversely placed across the five inoculums streaks. Plates without samples served as control. All the plates were incubated at 37° C for 24 h to 48 h. Post-incubation, the plates were examined for interruption of growth along with the streaks of inoculums beneath the specimen, and a clear zone of inhibition beyond its edge. The zone of inhibition was calculated using the formula given below:

$$W = T - D / 2$$

where W is the width of clear zone of inhibition in mm; T , the total diameter of the test specimen and clear zone in mm; and D , the diameter of test specimen in mm.

2.5.2 Determination of Antibacterial Finish on Filter Layer

The AATCC 100 test method (modified) was adopted for determining the triclosan finish on the filter layer through its ability in reducing the growth of bacteria. Triclosan filter layers of the sizes of 4.8 cm (diameter) were placed into sterile bottles and inoculated with 1.0 mL of *S. aureus* ATCC 6538 and *K. pneumoniae* ATCC 4352 at approximately 10^5 CFU/mL. The samples were incubated for 0h and 24 h at 37° C. At the end of incubation, the bottles were removed, added 100 mL of DE broth, shaken for 1 min, and then serially diluted (from 10^0 to 10^{-6}). From each dilution, 0.1 mL was plated in the nutrient agar plate in duplicates. Further, the plates were inverted and incubated at 37°C for 24 - 48 h. Screwcap bottles containing uninoculated sample swatches and untreated sample swatches served as controls. After incubation, using the colony counter, the colonies from each plate were counted and the percentage reduction was calculated using the formula given below:

$$(B - A / B) * 100$$

where B is the number of bacteria recovered from the inoculated treated test specimen at 0 h contact time; and A , the number of bacteria recovered from the inoculated treated test specimen after 24 h contact time.

2.6 Bacterial Filtration Efficiency Test

The bacterial filtration efficiency of the plain filter, triclosan padded filter and HME filter, compost of foam and filter layers were performed according to ASTM F2101. Briefly, Tryptic soy broth (10 mL) was inoculated with *S. aureus* ATCC 6538 and incubated at 37°C for 24 h. The culture was diluted in peptone water to achieve a concentration of 5×10^5 CFU/mL, which has a challenge delivery rate of 1700 - 3000 viable particles/sample. The challenge suspension was pumped through a nebulizer at a controlled flow rate (28.3 litres/min) with fixed air pressure. The generated aerosols were collected in Anderson samplers holding six cascade impactors with different pore sizes. The TSA plates were placed below each cascade impactor. Negative control sampling was done by collecting a 2 min sample of air from the aerosol chamber to confirm the sterility of the cascade. Similarly, positive control was performed with the challenge suspension for a minute without the samples to confirm the delivery rate of aerosol. The filters were placed above the cascade impactor and then exposed to bacterial aerosols for about a minute. Unfiltered aerosols were collected on TSA plates through a cascade impactor. All the plates were incubated at 37°C for 24 - 48 h. The colonies were counted and the percentage of bacterial filtration efficiency was calculated using the formula given below:

$$\text{Bacterial filtration efficiency (\%)} = (C - T / C) * 100$$

where C is the average plate count for test controls; and T , the average plate count total for the test sample.

3 Results and Discussion

3.1 Effect of Add-on on Moisture Vapor Transmission Rate of Hygroscopic Foam

The add-on weight in grams was determined with the help of moisture vapor transmission rates¹⁰. Three types of sourced foams were compared with the commercial filter towards the add-on weight in grams. The results are given in Table 2. The commercially available foam has 0.0163 grams as add-on weight when subjected to evaluation, whereas with the three

Table 2 — Test results for sourced and commercially available hygroscopic foam materials

Parameter	Foam with the existing commercial filter	Foam 1	Foam 2	Foam 3
Add on weight, g	0.0163	0.019 (P<.00001) S	0.025 (P<.00001) S	0.040 (P=0.00003) S
Moisture vapour transmission rate, g/m ² /24h	1635.0	1977.1 (P<.00001) S	1885.6 (P<.00001) S	1796.40 (P<.00001) S
Pressure drop kpa @ 60 LPM	0.1	0.1 (P=0.1496) N.S	0.1 (P=0.8732) N.S	0.1 (P=0.8005) N.S

different sourced foams, the foam of the third type (Foam 3) is found to have the best add-on of 0.040 grams; followed by the second (Foam 2) and first type (Foam 1) of foams, respectively at 0.025 and 0.019 grams. Based on the results, the third type of foam with a high add-on value is chosen for the construction of heat and moisture exchange filter. The size of open cells available with this foam and their thickness, along with the level of hygroscopic agents seems to fetch the best results and is found to be superior to the commercially available ones. Incoming air from the ventilator will carry the moisture observed from this foam during inhaling, thereby avoiding the problem associated with dry air.

3.2 Relationship between Airflow Resistance and Pressure Drop of Hygroscopic Foams

The pressure drop with foam available in commercial filters and sourced foam (from M/s. High Specification Products) has been characterized with the help of TSI Flow Meter and the results are presented in Table 2. The pressure which is required to attain a certain gas flow rate through it (the whole foam and filter device as such) is called pressure drop. In a real scenario, the level of airflow rate will be decided as per the tidal volume of the test person. The amount of air that is inhaled and exhaled by the lungs during one respiratory cycle is termed tidal volume. Usually, the pressure drop is measured using airflow rates such as 15, 30 and 60 L/min. This simulates the resistance offered by the foam material, concerning its hygroscopic coating available on its surface and the pore size associated with it. The pressure drop can be calculated using the following formula⁵:

Resistance offered to its flow = Pressure drop / Airflow rate

Based on the evaluation, the pressure drop of the hygroscopic foam is found about 0.1kPa at 60Lpm, which seems to be satisfactory; moreover, it is equivalent to the pressure drop available with the commercial one. Since the foam of the third type is

having higher moisture add-on and with equivalent pressure drop with respect to commercial one, the third type hygroscopic foam (Foam 3) is selected as a heat and moisture exchanger component.

3.3 Characterisation of Novel Composite Filters

Of the five different composite filter layers, the developed filters without meltblown nonwoven, having low g/m² and pressure drop are found to have low bacterial filtration efficiency BFE (a primary parameter required to characterize the filter).

Efficiency of different layer is given below:

Layer	BFE, %
3-Layers (SB-NP-SB biocide treated)	: 54.4
4-Layers (SB-SB-NP-SB biocide treated)	: 92.5
5-Layers (SB-SB-NP-SB-SB biocide treated)	: 96.6
4-Layers (SB-MB-NP-SB biocide treated)	: 99.0
5-Layers (SB-MB-NP-MB-SB biocide treated)	: 99.9
Commercial filter	: 99.9

It is obvious from the above results that BFE of 3 layer filter (SB-NP-SB), 4 layer (SB-SB-NP-SB biocide treated) and 5 layer (SB-SB-NP-SB-SB biocide treated) are less as compared to commercial filter (99.9%). Hence, three, four and five-layer filters (i.e without meltblown-MB) are not taken for further evaluation.

It is evident from the above results, that the 5 layers composite filter (SB-MB-NP-MB-SB biocide treated) have shown similar bacterial filtration efficiency to that of the commercial filter. Hence, further evaluations are carried out with this 5 layer composite filter material.

3.3.1 Weight/m² of Developed Filter Layers

Filtration happening at the patient's end is considered the most efficient way of safeguarding the entire breathing system⁷. In real cases, with a passive HMEF connected between the Y-piece and the catheter mount, the development of such a low weight disposable device with low airflow resistance play a vital role with the objectives intended with it.

Considering the above case, the developed composite filter material having a low weight per unit area along with a low pressure drop would be an added advantage. The evaluated results of the weight per unit area of the sourced nonwoven materials and the commercial filter are given in Table 3.

An exemplary filter possesses excellent filtration efficiency, without any resistance to the airflow, and one which has a higher level of safety owing to the existence of water and secretions. The most vital one seems to be the airflow resistance and pressure drop with it. Concerning the various types of filter availability, such as flat and pleated type, possessing small surface area and large surface area respectively; the area offered to the impaction of micro-organisms paves a crucial path for its flow. Since the compacted way of fibre arrangement with pleated fibre fetches a smaller pore size, with flat fibre surface area the matrix of fibre arrangement is less dense, leading to a great pore size¹¹. However, the resistance to airflow will be less with the flat type and more with the pleated one. To avoid this issue, the surface area of the pleated material is kept stretched, by maintaining the thickness at a minimum level⁷.

To compensate for this, we developed a composite filter in addition to the spunbond and meltblown, a needle-punched material, wherein the fibre compaction

is high concerning its fibre diameter and density, offering less resistance with improved filtration efficiency.

Owing to the flat surface of the developed filter materials, apart from the pleated type, the mechanism of filtration goes with the direct interception. Moreover, the inertia and momentum of the bacteria travelling in its straight path will be affected by inertial impaction. With respect to air borne particles and particulate matters, such an arrangement can result in increased airflow resistance. The same effect can be realized by inducing electrostatic attraction. However, due to higher dissipation of charge factors, the best results are not achieved¹¹. With our developed materials, instead of having a charged filter, the authors have come up with a biocide-coated one. This biocide treatment is not available there with commercial filters. With that as an advantage, a composite filter with three, four and five layers are arranged together and their efficiency is evaluated.

3.4 Morphological Analysis of Antimicrobial Filter with a Biocide Treatment

The Field Emission Scanning Electron Microscope images of biocide-treated and untreated spun bond layers are shown in Fig. 1. The spunbond nonwoven material treated with biocide shows deposition of

Table 3 — Properties of sourced and commercially available filter materials

Parameters	Sourced		Developed	Commercial sample	
	Meltblown	Spunbond	Needle-punched	Spunbond	Needle-Punched
Type of material	PP	PP	PP	PP	PP
Weight per square meter, g	21.20	27.48	278.37	24.20	300.90
Mean flow pore diameter, micron	11.45	68.68	63.92	66.64	53.31

*PP — Polypropylene fibre.

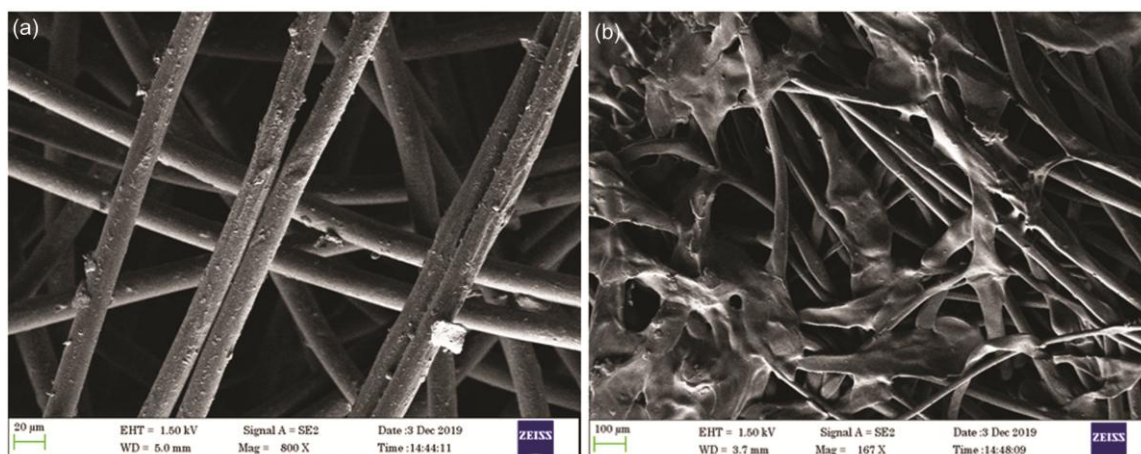


Fig. 1 — FESEM analysis of (a) untreated and (b) treated spunbond filter layer

biocide on the surface of the fibres forming a membrane that partially closes the voids between the fibres. Hence, while analyzing the mean pore size, it is found that the mean flow pore diameter of the treated material is lower when compared with the untreated one.

3.5 Combined Mean Flow Pore Diameter and Pressure Drop of Filters

The mean flow pore diameters are evaluated as per the in-house method with the help of a porometer instrument¹². The results of the sourced and developed single layers are given in Table 3.

While comparing the commercial sample without any treatment and the developed 3 layer biocide treated composite filter, it is observed that the pore size of the developed sample is found to be higher, owing to the pressure drop. As a result, the bacterial filtration efficiency is also lower.

Compared to commercially available filters, the four-layer biocide-treated composite filter with an additional meltblown layer shows a lesser combined mean pore size. However, its BFE does not show the levels of the commercial filter.

With the addition of two melt blown layers, in spite of lesser combined mean flow pore diameter of the developed 5-layer (SB-MB-NP-MB- SB biocide treated) filter, the pressure drop (Table 4) and bacterial filtration efficiency are found to be similar to that of the commercial filter.

3.6 Biological Characterization

Triclosan (2, 4, 4' -trichloro-2' hydroxydiphenyl ether) is a synthetic chlorinated bisphenol and non-ionic antimicrobial agent, which exhibits a broad-spectrum activity against a range of Gram-positive and Gram-negative bacteria, fungi and viruses. Triclosan affects the integrity of the microbial cell membrane by blocking the synthesis of lipids such as phospholipids, lipopolysaccharides and lipoproteins^{13, 14, 15}, thereby killing the microbes. This biocidal agent,

besides its applications in many consumer and professional healthcare products, has also been incorporated into textile fabrics and plastics. Polyester (CEL®, Ciba Specialty Chemicals), nylon (Tinosan AM 100®, Ciba Specialty Chemicals), polypropylene, cellulose acetate (Silfresh®, Novaceta) and acrylic fibres are some of the synthetic fibres where triclosan has been incorporated either as a finishing agent or during extrusion process and has been used for various applications. In the present study, an attempt has been made to explore the feasibility of using triclosan in HME filters to reduce microbial load during its usage and storage.

Different concentrations of triclosan (1, 2, 3 and 5 gpl) are padded on the nonwoven filter and then they are studied for their antimicrobial properties using *S. aureus* and *K. pneumoniae*. AATCC 147, a qualitative test method that detects the antibacterial activity of diffusible antimicrobial agents on the textile material, confirms the bacteriostatic activity of the nonwoven filter material padded with triclosan. Irrespective of the difference in the concentration of triclosan, the size of the zone of inhibition for *S. aureus* is found between 16.5 mm and 17.5 mm and between 11.4 mm and 12.7 mm in the case of *K. pneumoniae* (Table 5). But this is not the case in the quantitative assessment, where the triclosan padded filter achieves 99.99 % bactericidal activity by completely inhibiting the growth of both the organisms (Table 5).

Similar findings are also observed¹⁶, where the antibacterial and antiviral properties of 0.03 % triclosan-coated cotton fabric are studied along with 3 % sodium pentaborate pentahydrate and 7 % glucapone. The inhibition zones of microbial growth range from 16 mm to 46 mm against *E. coli*, *S. aureus*, *S. enterica subsp. enterica*, *S. epidermidis*, *K. pneumoniae*, *MRSA*, *C. albicans*, *A. niger*, and *T. mentagrophyte*. Triclosan coated on cotton fabrics through pad-dry and pad-dry-cure methods is studied for its antibacterial property against *S.aureus* and

Table 4 — Test results of developed composite filter material

Parameters	3-layer (SB-NP-SB)	4-layer (SB-MB-NP-SB)	5-layer (SB-MB-NP-MB-SB)	Commercial filter
Pressure drop kPa @ 60 LPM (Treated)	0.0965 (P<.00001) S	0.2275 (P=0.0001) S	0.3 (P=1) N.S	0.3
Combined mean flow pore diameter, micron (Treated)	34.279 (P=.00013) S	17.294 (P<.00001) S	12.503 (P<.00001) S	(-)
Combined mean flow pore diameter, micron (Untreated)	45.126	32.54	26.81	30.713
Composite filter layer (weight/m ²)	333.5	355.0	375.7	397.7

Table 5 — Assessment of antibacterial activity of triclosan padded nonwoven filter

Test organisms	Untreated	Spunbond/ Triclosan treated			
		1 gpL	2 gpL	3 gpL	5 gpL
AATCC 147					
<i>S.aureus</i>					
Bacteriostatic reactivity, mm	0	16.5	17.5	17.5	17.5
Growth under fabric	Present	Absent	Absent	Absent	Absent
<i>K.pneumoniae</i> AACC 4352					
Bacteriostatic reactivity, mm	0	11.4	11.7	12.2	12.7
Growth under fabric	Present	Absent	Absent	Absent	Absent
AATCC 100					
Bacterial reduction, %					
<i>S.aureus</i>	0	99.99	99.99	99.99	99.99
<i>K.pneumoniae</i>	0	99.99	99.99	99.99	99.99

*E.coli*⁴. When compared to chitosan-coated cotton fabric, triclosan-coated fabric exhibits profound activity against these organisms without affecting the physical properties of the fabric. Results of the present study confirm the antimicrobial properties of a filter, padded with triclosan, which has its application in the development of the HME filter.

The influence of triclosan padded on the bacterial filtering ability of HME filters is studied per ASTM F 2101 (modified). Filtration of bacterial aerosols is one of the key requirements of HME filters which should not get hampered by triclosan padding. The experiment was planned on a plain nonwoven filter, from commercial one, developed triclosan padded nonwoven filter and developed HME filter media, composed of foam and bacterial filter media (SB-MB-NP-MB-SB biocide treated). The bacterial aerosol used for the study was *S. aureus* and the mean particle size of the aerosol was $3.0 \pm 0.3 \mu\text{m}$. The limit of detection of the test system is 1 colony-forming unit (CFU) and filtration efficiency is 99.9 %. All three samples are found to filter bacterial aerosols with 99.9 % filtration efficiency. Further, to confirm the durability of biocide finish, HME filter stored for a period of about 2 years was tested for its antibacterial activity as per AATCC 100 test method. Results are found similar (Bacterial reduction 99.99% against both the bacteria) to that of the one tested earlier. Hence it may be inferred that (i) Padding method of triclosan is not hindering the bacterial filtration efficiency of the HME filter; (ii) bacterial aerosol which may cross the foam also get filtered through the bacterial filter kept next to the foam; and (iii) addition of bacterial filter protect the HME filter from the environment/patient mediated contamination.

The bacterial filtration efficiency of the commercially available filters and developed biocide coated

HME filters are found to be similar. Alternatively, commercially existing HME filters mostly works on the principle of attracting bacteria through electrostatic attraction on fibrous surfaces and bacteriostatic in nature. In the present work, bottom layer of HME filter is coated with the biocide that exhibits profound bactericidal activity against both Gram positive and Gram negative bacteria.

Coating of triclosan on the filter is mainly to impact biocidal property to the filter, thereby assisting patients from infections. To assess the release of triclosan on continuous exposure to the patients, the filter was exposed to aerosol at a flow rate of 28.3 L/min (Normal respiration rate of human) for about 4 h using BFE testing instrument. The aerosol passed through the filter was collected and were analyzed using GC-MS/MS to identify the release of triclosan from the filter. The results of GC-MS/MS confirm the absence of triclosan in the filtrate. This confirms that the possibility of triclosan release, even after continuous exposure for 4 h, is less.

4 Conclusion

This study demonstrates that the open-cell reticulated polyurethane foam with a hygroscopic agent helps to retain the heat and moisture from the exhaled air in an efficient way when compared to the commercially available filters. Triclosan coated nonwoven fabric (contact layer of oxygen) is found to be effective in killing pathogenic bacteria. Moreover, the 5 layer composite filter (SB-MB-NP-MB-SB biocide treated) is effective (BFE 99.9%) in filtering the bacteria under experimental condition. The pressure drop of developed filter is 0.3 Kpa at 60 lpm, comparable to that of commercially available filters. The durability of triclosan is found to be 2 years, as the filter stored for 2 years have shown antibacterial

activity similar to the earlier tested filter. Overall results of the present study confirms that the ability of the filter in maintaining heat and moisture and as a better substitute for imported filters. The results obtained have proven the effectiveness of the 5-layer bioactive treated HME-BF filters. With further clinical trials on patients, the efficacy of the filter can be enhanced and taken forward for commercial manufacturing.

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