Occupational Safety and Hygiene V

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Development of innovative clean air suits to increase comfort and simultaneously decrease operating room infections

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ABSTRACT: Comfort is a growing concern in medical textiles and specifically in medical clothing industry and must be considered when it's necessary to develop new products.

Specifically, in the surgical garment, gowns and clean air suits, is important to consider comfort as part of the requirements for any personal protective equipment or medical device, since the products are formulated to meet the primary requirement: the protection, according with the European standard EN 13795:2011+A1:2013: Surgical drapes, gowns and clean air suits, used as medical devices for patients, clinical staff and equipment. General requirements for manufacturers, processors and products, teste methods, performance requirements and performance levels.

Measuring comfort is difficult and this paper shows how to quantify comfort parameters using a thermal manikin for this specific PPE. For this study was made a quantitative analysis on two new developed clean air suits.

The results show that textile materials can provide a good comfort experience for the user and not compromise their function as a barrier material against operating room infections. With this study was possible to ensure a clean air suit with good protection, comfort and ergonomics features with the right balance between protection and comfort.

1 INTRODUCTION

In the present day, society expect much more from clothing than just to satisfy their basic needs (Das and Alagirusamy 2010). Textile Clothes are used as protective equipments for the body and they can protect the user in many different working areas. The healthcare sector uses several protective equipments and most of them are from textiles. Over the last years, a new range of materials and clothes to protect medical professionals and patients has emerging, improving the performance of medical clothing. The use of nonwoven based single-use materials like SMS (spunbond/meltblown/spunbond) ou spunlace that present a good resistance to liquid penetration, bursting and tensile strength or the common use of reusable laminated textile structures that offer good resistance to microorganisms and bacteria with bioactive or antimicrobial properties, making the clothing system a complete barrier to both professional and patient (Anand *et al.* 2006).

Clean Air Suits (CAS) are considered Class I medical devices according to the definition and classification rules of the Medical Devices Directive 93/42/EEC, amended by 2007/47/EC (Council Directive 93/42/EEC). Clean air suit is defined as a

“suit intended and shown to minimize contamination of the operating wound by the wearer’s skin scales carrying infective agents via the operating room air thereby reducing the risk of wound infection” by EN 13795:2011+A1:2013 (CEN 2011). The standard EN 13795 presents general performance requirements concerning properties which require assessment in CAS like resistance to microbial penetration, microbial and particle matter cleanliness, linting, bursting strength and tensile strength (CEN, 2011). As further characteristic of medical clothing, EN 13795 takes in consideration the comfort of the users but only as an informative note, in annex D. According the annex D thermophysiological comfort of a garment will depend on thermal resistance, air permeability, water-vapour resistance and drapeability (CEN 2011).

Inside of the Operating Room (OR), thermal comfort of medical clothing apparel is a very important parameter, since the lack of comfort can lead to thermal stress that influence the physic and psychological conditions of the surgeon, as the ability to maintain constant vigilance and concentration, which the correct surgical procedure is dependent (Hohenstein 2011, Abreu *et al.* 2015). Thermal comfort of the user depends on thermal properties and its adjustment to the environmental conditions in

the OR during the surgery, among many other factors like design, size and fabric characteristics (Cho *et al.* 1997). Extremely insulating and low absorbent medical apparel will result in an increase of skin temperature, leading to a greater moisture accumulation between the professional skin and clothing. To overcome this situation, surgical clothing needs to satisfy some requirements; they should be comfortable, breathable, loose fitting, keep the user in cool conditions and allow heat exchange changes between the body and environment (Fanger 1973, Song 2004).

Comfort can be understood as the set of sensations, body responses and reactions to several interactions of clothing. Comfort is a pleasant state of physiological, psychological and physical harmony between the human and the environment. For health professional can achieve thermal comfort, the mean skin temperature should be between 33°C and 34°C and sweating or chills should not occur.

In this way, the aim of the presented study was to compare thermal properties between two types of clean air suits, reusable and single-use, using a thermal manikin in a controlled environment.

The two clothing systems, reusable or single-use, must answer to primal function: protection. The ideal clothing system must ally protection and comfort all in one to allow the user to perform his job without any risks of thermal stress. To do so, comfort must be extended to all range of properties and characteristics such as sizing and design, textile materials choice and be focus on the user needs (Ribeiro *et al.* 2014).

The thermal manikin is an instrument for measuring the thermal insulation (I_{cl}) of garments and clothing ensemble. It is considered to be one of the most useful tools for evaluating thermal comfort of overall clothing systems, and the most studies about thermal clothing insulation occur with the use of thermal manikins. In comparison to other methods for measuring thermal properties of clothing, thermal manikin studies allow to investigate fully assembled clothing in the way these garments are supposed to be used (multi-dimensional), however without any influence of subjective interpretation of human testing or simply physical testing of the materials (bi-dimensional) (Vidrago & Abreu 2012).

To calculate I_{cl} there are three calculation methods – *serial*, *parallel* and *global*. As referred by Cho *et al.* (1997) and Oliveira (2008) the *global* method is the only one that is valid, despite of the common use of the *serial* and *parallel* calculation methods because it is the one less susceptible to thermal significant variations. In this study we use the three methods to compare two different clean air suits and see the significant differences and variations between calculation methods (Huang 2012).

2 MATERIALS AND EXPERIMENTAL METHODS

2.1 Clothing system

Disposable and reusable clean air suits were used in this study, Table 1. The reusable clean air suit (CAS-1) is made of a laminated structure with polyester (to the outside) and cotton (to the inside) with cotton cuffs. As for the single-use (CAS-2) we used the common SMS material, once it is the main material used for single-use clothing system. Both clothing systems were one piece design.

2.2 Thermal manikin and adiabatic chamber

Thermal manikins provide a good estimate of the total dry heat loss from the body and the distribution of heat flow over the body surface. In a standard environment, these measures can be used to describe the thermal characteristics of clothing (Oliveira 2008).

The thermal insulation of clothing ensemble was measured using a thermal manikin, Figure 1, with controlled skin surface temperature that simulates the wear. This thermal manikin, called “Maria”, has a woman’s body; its size and configurations are similar to an adult woman. It is divided in 20 thermally independent sections and only sense dry heat transfer. Thermal manikin, positioned 0.1 m from

Table 1. Tested clothing systems.

Ref/Type CAS	Design	Composition (%)	Weight (g/m ²)	Thickness (mm)
CAS-1- Reusable	Jumpsuit	50%PES/ 50%CO	139	0.28
CAS-2- Single-use	Jumpsuit	100% SMS	35	0.23

Figure 1. Thermal manikin: photo of nude thermal manikin used on tests (a) and software body picture of thermal manikin and color legend of body segments temperature (b).

Table 2. Operatic chamber

Temperature (°C)
Relative
Humidity (%)

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The tests w ber where an an operating t chamber can a 35°C and rela The test cond perature and r Room, accord

Data acquis ary conditions During the ac the skin temp every minute.

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3 RESULTS

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Table 2. Operating Theatre conditions tested in the adiabatic chamber.

Conditions in the adiabatic chamber				
Temperature (°C)	20°C	20°C	24°C	24°C
Relative Humidity (%)	40%Rh	60%Rh	40%Rh	60%Rh

the floor, was kept standing with their legs and arms held in vertical position without any motion. The skin temperature was set, and during the test period maintained at $33 \pm 0.1^\circ\text{C}$. Thermal manikin operates with the constant skin temperature regulation mode. The constant skin temperature regulation mode was used (Cho *et al.* 1997).

The tests were conducted in an adiabatic chamber where ambient conditions characteristic of an operating theatre were simulated. The climatic chamber can achieve temperatures around 15°C to 35°C and relative humidity around 35% to 85%. The test conditions performed simulate the temperature and relative humidity inside an Operating Room, according to Table 2:

Data acquisition started after achieving stationary conditions and did not take more than 60 min. During the acquisition period, the heat flux and the skin temperature of each body part record every minute.

The three thermal insulation calculation methods—the serial, the global and the parallel—were considered to calculate thermal insulation (I_T) in order to compare the different test methods and the different clothing systems behaviour. Calculation of the Thermal insulation (I_T) according to global, parallel and serial method.

3 RESULTS

The results presented were related to two clothing systems: a reusable clean air suit, made of 50%PES/50%CO and a single-use clean air suit, made of SMS material. Table 3, 4, 5 and 6 shows the values of thermal insulation of the thermal manikin nude (reference) and dressed with each suit, for the four OR simulations of temperature ($^\circ\text{C}$) and relative humidity (%).

According with Nilsson (1997) referred by Oliveira (2008) *serial* method present the highest values of thermal insulation once the differences between *serial* and *parallel* method increase with non-uniform insulation. So for this we can expect higher values for I_T when used *serial* method. The difference between these two methods can amount to 30% or more. Holmér (2001) also referred by Oliveira (2008) said that *serial* method overestimates the insulation values.

As we can see, for the temperature of 20°C and relative humidity between 40% and 60% the clothing system with the best thermal insulation values is CAS-1, that present the lowest values of thermal insulation in all three calculation methods. As expected the values of thermal insulation for reusable CAS-1 are lower. This clothing system is made of reusable textile materials and the heat flux is well conducted through this materials that is translated to the sensation of freshness/coolness by the user. Higher the value of thermal insulation, more the user will heat and sweat, so lower values of thermal insulation are always best. Although CAS-1 presented the best results and the lowest

Table 3. Results of thermal insulation for all the conditions $T = 20^\circ\text{C}$ and 60% Relative Humidity, and the three calculation methods.

	T 20°C Hr 60%		
	Global method	Serial method	Parallel method
Nude			
Ia [m ² .°C/W]	0,092	0,106	0,092
Ia [m ² .K/W]	0,096	0,106	0,092
Clo	0,620	0,680	0,592
CAS 1			
It [m ² .°C/W]	0,130	0,153	0,129
It [m ² .K/W]	0,136	0,153	0,129
Clo	0,878	0,985	0,830
CAS 2			
It [m ² .°C/W]	0,153	0,189	0,152
It [m ² .K/W]	0,160	0,189	0,152
Clo	1,031	1,221	0,983

Table 4. Results of thermal insulation for all the conditions $T = 20^\circ\text{C}$ and 40% Relative Humidity, and the three calculation methods.

	T 20°C Hr 40%		
	Global method	Serial method	Parallel method
Nude			
Ia [m ² .°C/W]	0,111	0,124	0,111
Ia [m ² .K/W]	0,116	0,124	0,111
Clo	0,749	0,797	0,715
CAS 1			
It [m ² .°C/W]	0,170	0,199	0,169
It [m ² .K/W]	0,177	0,199	0,169
Clo	1,140	1,286	1,088
CAS 2			
It [m ² .°C/W]	0,183	0,220	0,182
It [m ² .K/W]	0,191	0,220	0,182
Clo	1,233	1,422	1,174

Table 5. Results of thermal insulation for all the conditions T = 24°C and 60% Relative Humidity, and the three calculation methods.

	T 24°C Hr 60%		
	Global method	Serial method	Parallel method
Nude			
Ia [m ² .°C/W]	0,110	0,126	0,109
Ia [m ² .K/W]	0,117	0,126	0,109
Clo	0,753	0,811	0,705
CAS 1			
It [m ² .°C/W]	0,158	0,190	0,156
It [m ² .K/W]	0,167	0,190	0,156
Clo	1,078	1,226	1,009
CAS 2			
It [m ² .°C/W]	0,174	0,218	0,173
It [m ² .K/W]	0,185	0,218	0,173
Clo	1,192	1,409	1,117

Table 6. Results of thermal insulation for all the conditions T = 24°C and 40% Relative Humidity, and the three calculation methods.

	T 24°C Hr 40%		
	Global method	Serial method	Parallel method
Nude			
Ia [m ² .°C/W]	0,089	0,097	0,089
Ia [m ² .K/W]	0,095	0,968	0,089
Clo	0,612	0,625	0,573
CAS 1			
It [m ² .°C/W]	0,161	0,182	0,160
It [m ² .K/W]	0,172	0,182	0,160
Clo	1,110	1,171	1,034
CAS 2			
It [m ² .°C/W]	0,178	0,202	0,177
It [m ² .K/W]	0,188	0,202	0,177
Clo	1,213	1,305	1,141

I_T values, both clothing systems present very close values which means that in an OR situation they would serve to the user as well.

4 CONCLUSIONS

The aim of this study was to compare thermal insulation of two clean air suits with the same design made of different materials: reusable (woven fabric) and single-use (nonwoven fabric) using a thermal manikin using different calculation methods. Thermal manikins provide a good estimate of the total dry heat loss from the body and the distribution of heat flow over the body surface. Both measures

are used to describe the thermal characteristics of clothing. The results obtained with the three calculation methods of the thermal insulation showed that values of the *serial* method were always the highest, as expected and the *parallel* method always present the lowest values. *Global* method is less susceptible to significant variations and it should be used for calculating thermal insulation of clothing for all manikin control modes, especially for thermal comfort regulation mode (Cho *et al.* 1997).

The difference between wearing CAS-1 or CAS-2 are not very significant, however CAS-1 presented better results of I_T and best performance due to heat loss, meaning that CAS-1 materials have a good influence to the thermal behaviour of the clothing system.

We can conclude that several factors can influence thermal insulation of clothing such as the fabric characteristics, drapeability, sensitive touch, fit, sizing and others. So, comfort is a requirement that have to be consider when talking about clothing systems to operate as medical devices (non-active) or personal protective equipment in order to get to the user a good comfort experience.

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