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DESIGN AND DEVELOPMENT OF INNOVATIVE NON ACTIVE MEDICAL DEVICES: CLEAN AIR SUITS

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Abstract: *Design fitting and comfort are an important subject to consider when we need clothes for protective and individual equipment. Construction of protective equipment requires ergonomics, fabrics and performance requirements studies.*
This paper is about the construction of clean air suits (CAS) for use in the operating room. This suits were developed to minimize the contamination in operating rooms. It's important to develop clothing with good protective barriers, however attention must be given to comfort to obtain a suit that answers effectively for both protection and comfort requirements.
Our study consists in selecting the best fabrics, woven and non-woven, that could manage protective and comfort requirements.
We're developing several designs, in order to foreseen the best design approach to a clean air suit. Normally these kind of suits need to be closed at the bottom legs and sleeves in order to minimize skin particles dispersion.
Keywords: *comfort, protective equipment, clean air suit, design*

1. Introduction

In the present day society, except much more from clothing that to satisfy our basic needs [1]. Clothes are used as protective equipments and they are necessary to protect the user, in many different areas. Healthcare sector makes use of several protective equipments and most of them using textiles. Over the last years, a new range of materials and clothes for protect medical professionals and patients has emerging, improving the performance of each medical clothing. This paper has the purpose to explain an overview of product design process orientated for healthcare sector, in particular the concept and development of clean air suits.
When we work with protective clothing it's necessary to follow standard guidelines in order to respond all the performance requirements.
In this case study we are using the performance requirements for CAS referred in 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, test methods, performance requirements and performance*.
By definition, CAS is 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. [2]
Minimize contamination is an important question when we talk about medical clothing and infection control. A major part of the spread of potential infection can be stopped using the right clothes with the right textile materials. So it's necessary to select the most effective materials to achieve protection on both patient and professional and cleanliness of the operating rooms and hospitals in general.
However protection is an priority requirement, comfort of the professionals, patients must not be forgotten and the choice of textile materials has to be taken consider the two mayor concerns: Protection and Comfort.
In order to do a complete study about these kind of suits we need to study all comfort properties, like evaluating thermal insulation, water and air permeability, friction behavior, between other properties. When thinking about design and ergonomics it's very important to consider, already mentioned, the comfort, a concept that sometimes is forgotten by the manufacturers during the design process .
Comfort it's a difficult word to describe sensations, ambiences, body responses and reactions to several types of clothing. We can say that comfort it's a pleasant state of physiological, psychological and physical harmony between the human and the environment [3]. By this definition we must develop medical clothing based on protection requirements however we must not forget comfort requirements, creating a good and effective solution for the medical sector. To the design fitting we consider a CAD system developing the right patterns. Normally these kind of suits need to be closed at the bottom legs and sleeves in order to minimize skin particles dispersion, from the body to outside and other wise. So here it's important to adequate the right sizes to the right body in order to prevent infection. The design process needs to be well planned and all steps should be according with performance requirement for protection and comfort, pre-established by the manufacturer.

2. Methods

2.1. Materials

In this study we tested several reusable materials, once the reusable have more advantages then single use materials for the focus on comfort.
Reusable materials can be used many times, have good breathability, a better touch that single-use materials and they have good opacity (transparency concerns). They also have some disadvantages because reusable fabrics have more weight and some fabrics have linting problems (Figure 1A) (counts of colony-forming units are low- cfu/m^3). We need to think that when we use a reusable fabric its necessary to re-process them and sometimes make a re-esterilization, which means reprocessing costs for hospitals to care.

Figure 1 – Linting: a.Fabric with linting, b. Fabric without linting

Single use materials can also be used once they have very low levels of linting (Figure 1B) and offer a high level of cleanliness and hygiene. They are very thin and light and we can find it easily in the market, because single-use products are becoming more and more requested. On the other hand we can only use a single-use product once, and this could be a expensive aquisition to a hospital too. They don't have good flexibility so they can't adapt so good to the human body. They have a low moisture management so the comfort properties aren't so good.
After seeing the pros and cons of reusable and single-use materials we chose reusable fabrics to test and improve comfort in clean air suits.
We tested sensorial properties related to touch and thermal properties related to the sensation of fresh and cool when we dress a clean air suit or other medical clothing.
We also study a few clean air suits in a thermal manikin to see the thermal insulation values to determine if they are too warm or to fresh.

2.2.Protection and Comfort

For the construction of a CAS it's necessary to follow some performance requirements, presented in the standard EN 13795 (table 1).

Table 1 – Characteristics to be evaluated and performance requirements for clean air suits [4].

Characteristic	Test method	Unit	Requirement[b]
Resistance to microbial penetration – Dry	EN ISO 22612	CFU	≤300 [a]
Cleanliness – Microbial	EN ISO 11737-1	CFU/ 100 cm^2	≤300
Cleanliness – Particulate matter	EN ISO 9073-10	IPM	≤3,5
Linting	EN ISO 9073-10	Log_{10} (lint count)	≤4,0
Bursting strength – Dry	EN ISO 13938-1	kPa	≥4,0
Tensile strength – Dry	EN 29073-3	N	≥20
[a] Test conditions: challenge concentration 10 8 CFU/g talc. and 30 min vibration time. [b] Performance requirements apply for all product areas of clean air suits.			

Linting consists in release of fibre fragments and other particles during handling and use. These garments and particles are originally from the fabric itself. The linting problem is very important and when choosing the right materials for the suits it's necessary to measure linting release. Once we measure linting we must choice the fabrics with the lowest values, that would help to control the release particules from the material and make the operating theater and hospitals more clean and therefore more hygienic.
Another important matter about the fabrics we choose is the diameter of the pores of the fabrics, because the release of skin scales that wearer's release too, carrying infective agents.

Reinmüller made a study [5] in several different fabrics in order to evaluate which are the most effective fabrics to minimize the loss of skin scales by humans (table 2).

Table 2 - Comparison of data of the source strength from people dressed in various clothing systems laundered once, 25 times and approximately 50 times, respectively. Ljungqvist and Reinmüller (Ljungqvist and Reinmüller, 2013)

Clothing System	Contaminant	Number per second		
		1 wash	25 washes	Approx. 50 washes
Surgical clothing System Cotton(69%) Polyester (30%) carbon fiber (1%)	particles ≥0.5 µm	-	-	29 467
	particles ≥5 µm	-	-	1 653
	particles ≥10 µm	-	-	608
	CFU	-	-	10.9
Surgical clothing System Cotton(50%) Polyester (50%)	particles ≥0.5 µm	4 060	13 875	12 207
	particles ≥5 µm	270	535	698
	CFU	1.7	4.2	9
Single-use surgical clothing polypropylene antistatic treated	particles ≥0.5 µm	1 072	-	-
	particles ≥5 µm	113	-	-
	particles ≥10 µm	53	-	-
	CFU	2.5	-	-
High quality cleanroom clothing system polyester (100%)	particles ≥0.5 µm	585	3 950	2 860
	particles ≥5 µm	9	70	36
	CFU	0.4	0.5	1.1
High quality cleanroom clothing system polyester (99%) carbon fiber (1%) and undergarment polyester (100%)	particles ≥0.5 µm	-	143	153
	particles ≥5 µm	-	7	10
	CFU	-	<0.2*	<0.2*

Easily we can notice that single-use surgical clothing has no cfu which are a good property for single-use materials. When thinking about reusables, woven fabrics, we can also see that the level of cfu is also very low, when the fabrics are developed specifically for medical area. Talking about reusable means that the suits are intented to be used many times, and if so, we need to guarantee that after 25 washes the fabric still have good properties and that they guarantee at least 50 washes to maintain performance levels.
About the protective requirements, they are described in the NP EN 13975 but comfort requirements aren't and they are also important and need also to be quantified and evaluated. Quality of garment touch, breathability, air permeability, thermal properties and fabric drape are requirements that we must pay attention, because professionals have comfort problems with the medical clothing already made, once they focus is more on protection and not on comfort. Nowadays we can see that many users are complaining about heat issues and lack of breathability in medical clothing that they need to use everyday, many hours per day. This seems to be an easy problem to solve, however it's hard to find good materials with both protection and comfort properties.
This problems reflects the need to research for new materials and designs for clean air suits and other medical clothing devices once there are new materials and new ways to improve protection in a textile material. Also talking about comfort there are new materials too.

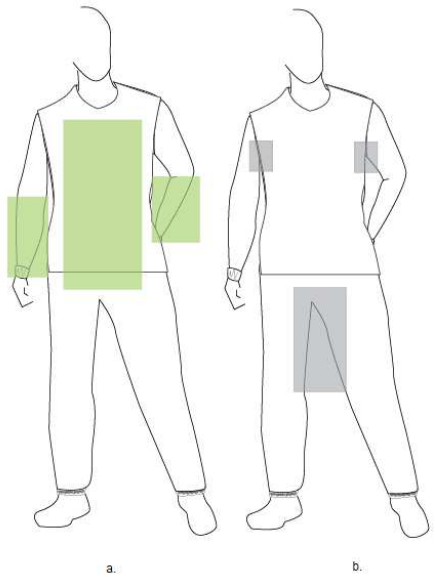

Figure 2 – Important body areas: a. Protection areas; b. Comfort areas

In order to make a good design all this properties are important for the user: protective, comfort and aesthetic issues need to be consider in the development of a medical clothing. Talking about protection and comfort its easy but its necessary to define which are the protection zones (Figura 1-a) and the comfort zones (Figure1-b).
Protection areas need to have good barrier textile materials in order to prevent against resistance to microbial penetration (dry), bursting and tensile strenght (dry) protecting the professionals.
For the comfort areas we need to think of a way to reduce heat and sweating, keeping the user dry and fresh for his work performance.
The properties for comfort can be evaluated through a series of equipments, although many people think that is difficult to measure. After measuremtens it's important to correlate the data and understand the meaning of the values in practical therms.

2.2. Design and Fitting

We started to put together a raw of different single use and reusable materials to evaluate them and see what are the best fabrics and why.
The reusable fabrics that we gather are 100% polyester with carbon yarn (giving anti-static properties), and the single use one is polypropylene.
We have the opportunity to see other clean air suits already made and sold in the market and we also study and test them. To do a product we need to do a benchmarking study and see other similar products in the market, understanding the advantages and disadvantages of each one. With a brainstorming session we develop and improve design processes. Getting back to the textile materials is one step that is essencial and testing its properties is imperative to forecast a good product. Design is algo an essential step because if you have a good textile material, but a poor design the product will loose qualities.
After we select the materials it´s necessary to work on the patterns and fitting questions. The patterns are simple and with straight cuts, however we need to to conceive the neckline, thinking that man and women have different constraints and different bodies. Sizing is a question that defines if the suits are or not fullfilling the protection requirements. Because the clean air suit must be closed up, at the ends of the upper part and pants. However if your size is S (small) and you'll ve given a L (large) or a XL (extra-large) the cuffs will not do the work. Also for comfort an oversized suit can increase the friction between the skin and the textile material, generating other problems. It's imperative that the user use a clean air suit with the right sizes. Also we must pay attention to other details such as the size of the upper part, trousers and the pockets, the length of sleeves and width of torso. Sometimes we see medical clothing with lack of appropriate sizes for each professional, making them more uncomfortable and even disrupt their work.
Also, we can improve the way of dressing the suits and make them more easy to dress/undress. Here, it's important to have prototypes and make a quick study detecting the mistakes and make some adjustments.

3. Design Development

We evaluated a couple of clean air suits from different brands and detect areas to intervene, making some changes that we think are need it. All the clean air suits were two pieces made and this kind are the easiest to dress/undress. All them were made in reusable fabrics and presented a nice touch and they present a good barrier protection, which is important. However some of CAS were to heavy and warm. Also, the cuffs were not to soft, making us think that the pressure would become difficult to handle in a operating room.
In the present design process,seeing all the CAS we detected a lack of comfort. All products have good protection performances however none has really concern about the comfort of humans when dress the CAS. This matter can be understand because the focus is on protection, according with the standard. But design today is concern with all properties that ensure a good experience for the user and his relation with the medical clothing.

Our focus is developing a good CAS that attend to all protection requirements having a new improvement, textile materials that solve comfort problems. After our brainstorming and tests in all materials we think of making a CAS and consequently it's necessary to make experiences to see the materials behavior that we select in practical terms and see if its necessary to change it or not.
This CAS has to have a great protection barrier and a good process thinking about the sizing and fit of the two pieces or a even more thinking issue if we speaking of one piece CAS.
When we construct the patterns for the clean air suit, then we need to put good thinking about the cuffs. The elastic limits are a very important detail for the comfort of the suit and it has to be tight at the same time. But not too tight, because if the cuffs are too tight the pressure in sleeves and ankles will turn to be uncomfortable.
Once the suit is made it's necessary to test it in real conditions, in operating rooms, with real users.

4. Results

Reusable materials were tested in different equipments to measure comfort properties so that we could understand the textiles behavior in conditions similar to the operating rooms.
We tested different reusable materials with properties that improve comfort in the critical comfort areas showned above, in figure 2. These materials, mostly made of polyester and carbon yarns, have very acceptable values on thermal insulation, which means that they can make the user more cooler in the operating room. The lowest value of thermal insulation means that the textile fabrics evaluated are coolest then the normal fabrics used in medical clothing which makes the CAS more fresh to the user. The thermal insulation measured in the thermal manikin was also very interesting because we could see which CAS were more coolest, during the simulation of the operating room conditions.
Air permability and water vapour permeability also had good values that show a good management of sweat and heat, because the air easily pass through the materials.
So we can make a good CAS focused on breathability properties and fullfill comfort requirements. These materials also are according with performance requirement in the standard so we think this could be a good way to solve the lack of comfort without the concern of not pass the standard-barrier properties.

5. Conclusion

Medical clothing is always a difficult area to improve changes because users are more concern about protection issues and maintain the operating theater hygienic and clean, preventing nosocomial infections that cost, every years, millions to hospitals and other healthcare facilities. But the change is need it. Medical clothing needs to be more comfortable to the users once they spend many hours with the uniforms/gowns/scrub suits/clean air suits because some users are complaining about heat, sweat and perspiration. It's up to designers take this complains, think of the barrier requirements and include comfort in it. When we solve the lack of comfort in this medical clothing systems we come up with an improved clean air suit that answers to both protection and comfort.
Objective testing its necessary to evaluate protection properties and levels of performance and to evaluate comfort properties in order to choice the best materials (reusable or single-use) and maybe possibilities to combine more than one material together.
After the selection of the materials it is important to pay attention to CAS design, options to see the best ways to dress/undress, different types for sleeves and cuffs. The design process is very important because a bad design could compromise all comfort improvements.
We must test the CAS in real operating theater conditions, so it's interesting to give opportunity to users test it, first hand. The user has the better impression and could contribute with very good information about the suits. It's easy to see on real body if the sizing are appropriate or not, and if not is necessary go back to patterning and make adjustments again. Right sizing is really important too.
In a general way all the steps are important and must be thinked always considering two important variants: comfort and protection. The ideal clean air suit, or any other medical clothing, has to have a balance between comfort and protection characteristics. The user must feel the medical clothing as a second skin, and not be irritated by it.
Healthcare and medical setor rised up questions related to comfort of the user. So we need to pay attention and be the first to solve this problems with a good design process and good knowledge of standards, ,textile materials and testing equipments.

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