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Characteristics, Protection and Functional Design of Three-Layer Laminate for Medical Footwear

Značilnosti, zaščita in funkcionalna zasnova trislojnega laminata za medicinsko obutev

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Abstract
The aim of this paper is to determine the influence of the washing and sterilization process in real hospital conditions on the microbial barrier properties of textile laminate used in medicine for protective clothing. The paper focuses on the functional design of three-layer laminate for medical footwear in surgery and in rooms where aseptic working conditions are required. The permeability and durability of the microbial barrier were determined after 0, 10 and 20 washing and sterilization procedures according to previously developed methods. Bacterial endospores of apathogenic species of the genera *Geobacillus stearothermophilus* and *Bacillus atrophaeus* were used. A functional design of the protective shoe cover was proposed. The results showed an extremely effective microbial barrier and the durability of the sample after 0, 10 and 20 washing and sterilization procedures, and over a period of one, two and three months.
Keywords: microbial barrier, three-layer laminate, medical footwear, functional design

Izvleček
Namen članka je bil ugotoviti vpliv pranja in sterilizacije v realnih bolnišničnih razmerah na mikrobiološke barierne lastnosti tekstilnega laminata, ki se uporablja za medicinska zaščitna oblačila. Predstavljena je funkcionalna zasnova trislojnega laminata za medicinsko obutev v operacijskih dvoranah in drugih prostorih z aseptičnimi delovnimi razmerami. Prepustnost in obstojnost mikrobne bariere sta bili določeni po nič, desetih in dvajsetih pranjih in postopkih sterilizacije po predhodno razvitih metodah. Uporabljene so bile nepatogene bakterijske endospore iz rodu Bacillus, Geobacillus stearothermophilus in Bacillus atrophaeus. Predlagana je bila funkcionalna zasnova zaščitnega pokrivala za čevlje. Rezultati po nič, desetih in dvajsetih postopkih pranja in sterilizacije ter v obdobju enega, dveh in treh mesecev odležanja vzorcev so pokazali izjemno učinkovito in obstojno mikrobno bariero.
Ključne besede: mikrobna bariera, trislojni laminat, medicinska obutev, funkcionalna zasnova

1 Introduction

Textile laminate is a two- or multi-layer textile material that is connected with a polymer layer to form a whole. The substrate on which the polymer layer is applied can be woven, knitted or non-woven fabric. Polyurethane (PU) is a multi-purpose coating polymer used to coat protective clothing [1, 2]. The laminate properties are a combination of the properties of the base fabric and the polymer layer. The result of such a combination provides many properties that the individual components cannot provide. The substrate or base fabric gives the composite material mechanical strength and carries the coating layer applied to it. High-quality coated fabrics require high-quality base woven and knitted fabrics [1–5]. The polyurethane (PU) polymer layer gives the laminate the property of liquid impermeability and the possibility of water vapour transfer from the body into the environment [6–8]. Due to the comfort of the microporous structure, which allows breathing, and the possibility of passing through the sterilization medium, polyurethane (PU) is an acceptable material for a wide range of medical applications [9, 10]. Medical textiles belong to the group of technical textiles and include all textile products used in medicine, gowns, caps, medical footwear, etc. Conditions of application, i.e. multiple washing and sterilization damage the textile material, which limits its use [11]. In order to meet medical standards, reusable medical textiles must, with regard to the purpose, meet some of the basic conditions, such as being impermeable to microorganisms, being biocompatible, having the possibility of chemical and thermal sterilization, ensuring the stability of shape and dimensions; having the possibility of rational and economical production, etc. [12]. Washing or dry cleaning and sterilization allow their reuse. Reusable medical textiles are more cost-effective on account of cost reduction. How long they are used depends solely on the efficiency of the microbial barrier and mechanical properties where they are needed [13]. The function of medical textiles is often to protect against bacteria and viruses originating from staff and patients. They must be free of toxic ingredients, maintain integrity and durability, and withstand the physical conditions of standard stress during use [2, 12]. Manufacturers do not recommend woven fabrics and knits as an adequate barrier for use in medicine if they are single-layered and without surface treatment because their pores are far larger than microorganisms. However, woven and knitted fabrics are still the most commonly used textile materials for medical purposes [14, 15]. Polyurethane (PU) is one of the specific polymeric materials widely used in various fields and even in medicine for medical synthetic materials and dressings due to its exceptional properties, such as softness, comfort to touch and long-lasting pressure, and balance of mechanical properties, especially when sandwiched between textile fabrics [16]. By selecting the appropriate properties of the components in the layers of the laminate, exceptional properties can be achieved that can satisfy a variety of medical applications.

The aim of this research was to determine the influence of washing and sterilization on the permeability and durability of the microbial barrier of a three-layer laminate PES (woven fabric)/PU/PES (knitted fabric) for strong and durable medical footwear. Changes were identified after 0, 10 and 20 washing and sterilization processes under real hospital conditions. The durability or retention time of the microbial barrier of sterilized, diagonally packed laminate packages (EN ISO 11607-1 2009) was determined after storage over a period of one, two and three months under real hospital conditions [17]. The aim of this work was also to create a functional design of a three-layer laminate for medical footwear.

2 Experimental part

2.1 Materials and methods

A three-layer textile laminate made of PES/PU/PES and produced at the company Čateks in Čakovec, Croatia (Table 1) was used. The front side of the fabric sample is woven in plain weave, while the back side consists of knitted fabric. There is a polyurethane layer between the woven and the knitted fabric. The samples shall be used for medical purposes.

Table 1: Basic parameters of the three-layer PES/PU/PES laminate

Sample	Composition	Structure	Mass per unit area (g/m^2)	Thickness (mm)
PES/PU/PES	1st layer	100% PES woven fabric, plain	213.84	0.42
	2nd layer	100% PU		
	3th layer	100% PES knitted fabric, tricot		

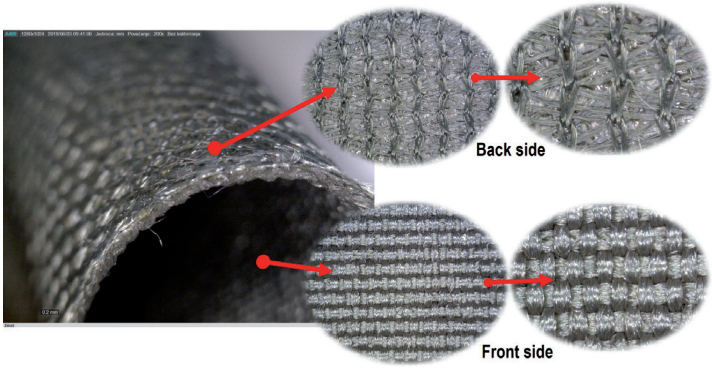

Figure 1: Surface view of the PES/PU/PES laminate

Figure 1 shows the surface of the three-layer PES/PU/PES laminate from the front and back side.
The washing and sterilization procedures were carried out in the specialized laundry unit of the Clinical Hospital Centre Zagreb – Rebro. The sample was washed in a continuous washing machine (JENSEN brand) according to a specially defined procedure (see Table 2) [18]. The sample was sterilized in a Selectomat PL MMM hospital steam sterilizer (Münchener Medizin Mechanik) at 134 °C and at a pressure of 2.5 bar for five minutes. The samples were sterilized after each washing cycle.

Table 2: Washing parameters

Washing solution	0.7 g/kg Ce; 2.5 g/kg Ca
Disinfecting agent	4 g/kg Cc
Temperature (°C)	60
Bath ratio	1:5

Commercial names of all products are not given due to the confidentiality of the participating laundry and the impartiality of the research. Ca – polycarboxylate (< 5%), sodium hydroxide (10–20%). Cc – ethoxylated fat alcohol < C15 & < 5 EO (25–30%), solvent, 2-propanol, methanol (0.1–0.25%), amphoteric surfactants (1–2%), additives (0.1–0.25%). Ce – formic acid (50–100%).

2.2 Microbial barrier properties

Samples are packed in sterilization packages and sterilized at 134 °C for five minutes (number of the samples: 18). Microorganisms are then applied to the samples under aseptic conditions by rubbing on the sample surface. The application of microorganisms is followed by incubation for 24 hours. After incubation, prints are taken with a CT3P agar plate. First from the back side, then from the front side. A 72-hour incubation at 35 °C is then performed, followed by the counting of bacterial colonies (CFU) [19].
Figure 2 shows a schematic representation of the testing of microbial barrier properties.
The bacterial spores of the genus *Geobacillus stearothermophilus* and *Bacillus atrophaeus* were used as the only dry-type microorganisms. The use of a suspension moistens the fabric and the permeability is altered [18].

2.3 Microbial barrier durability testing

The tested samples (22 cm x 22 cm) were packed in packages after 10 and 20 washing cycles (Package number: 60). Gauze was packed into each package, under which absorbent paper “Whatmann No. 1” of 1 cm2 was placed. The packed packages were sterilized (134 °C for five minutes) and placed in a protected

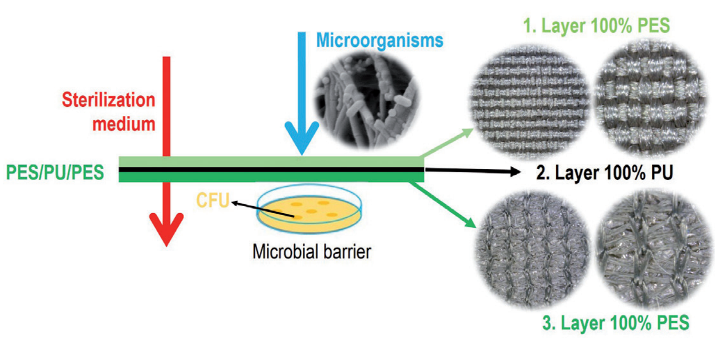

Figure 2: Microbial barrier properties testing

warehouse with a temperature of 15–30 °C and a relative humidity of 30–60%. The storage time of the packages was one, two and three months. After the specified time, the packages were removed from the warehouse and unwrapped under sterile conditions. Using sing tweezers, the absorbent paper was removed from the package and placed in a test tube with a Brain-Heart broth. After incubation for 48 hours at a temperature of 35 °C, a change in the visually clarity of the broth was observed, i.e. whether turbidity has occurred. The sterility was additionally checked by fitting on a solid nutrient basis, while 5 ml of Brain-Heart broth was planted on an agar containing 5% sheep blood. After 48 hours of incubation at 35 °C, the number of bacterial colonies was observed [19].

3 Results and discussion

Due to the washing and sterilization procedures, a three-layer textile PES/PU/PES laminate shrinks. This, in turn, results in an increase in fabric thickness. A change in mass per unit area and thickness was determined according to the relevant standard and is shown in Table 3 [20, 21].

Table 4 shows the number of microorganisms on the front and the number of microorganisms passed through to the back. The number of microorganisms on the surface represents the number of microorganisms remaining on the surface of the sample after bacterial endospores of pathogenic species of the genus *Geobacillus stearothermophilus* 10^5 and *Bacillus atrophaeus* 10^6 were rubbed with a stick.

In the PES/PU/PES sample, there was a 3.8-fold increase in the number of microorganisms absorbed on the surface (283 CFU) compared to the initial values (74 CFU). However, despite the growth of microorganisms on the front of the sample, there was no leaking of microorganisms on to the back. It can be concluded that the increase in retained microorganisms on the surface layer is due to the rough surface after 20 washing and sterilization cycles. One of the reasons for the impermeability of the microbial barrier is the polyurethane layer present in the sample. The rougher surface has the ability to retain a larger number of microorganisms, which is evident from the results obtained (see Table 4). The durability of the microbial barrier was determined using the method of sterilized diagonally packed packages (one layer; EN ISO 11607-1: 2009) after storage for one, two and three months. The results of the testing of the durability and efficiency of the microbial barrier over one, two and three months after a series of 10 and 20 washing and sterilization procedures are presented in Table 5.

The testing results of the durability of the microbial barrier over a period of one, two and three months show a satisfactory durability of the microbial barrier of the textile laminate. There was no contamination of the contents of the package. The impermeable microbial barrier is very important for use in medicine and other sterile areas.

Table 3: Results of the design parameters of the three-layer laminate

Sample	Washing and sterilization cycles	Mass per unit area			Thickness		
		Mean (g/m^2)	SD[a] (g/m^2)	CV[b] (%)	Mean (mm)	SD[a] (mm)	CV[b] (%)
PES/PU/PES	0	213.84	2.43	1.14	0.42	0.01	1.76
	10	217.44	1.56	0.72	0.45	0.01	3.17
	20	214.12	2.47	1.16	0.44	0.01	1.29

[a] standard deviation; [b] coefficient variation

Table 4: Microbial barrier test results

Sample	Number of isolates	Washing and sterilization cycles	The average number of bacterial colonies on the front side (CFU)	The average number of bacterial colonies on the back side (CFU)
PES/PU/PES	6	0	74	0
	6	10	240	0
	6	20	283	0

Table 5: Results of microbial barrier durability testing after one, two and three months, and after 10 and 20 washing and sterilization procedures

Sample	Washing and sterilization cycles	Testing after (months)		
		1	2	3
PES/PU/PES	10	NMR[a)]	NMR	NMR
	20	NMR	NMR	NMR

[a)] *no growth in microorganisms in the package*

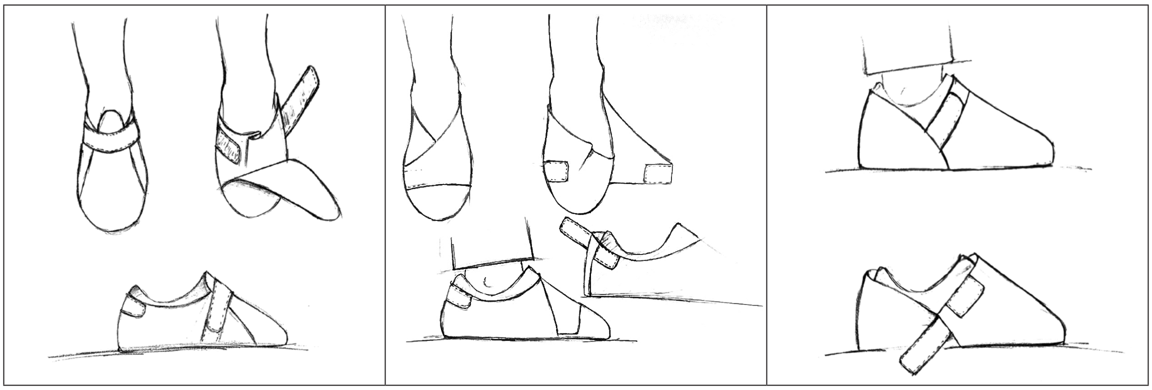

Figure 3: Functional design of three-layer laminate for medical footwear

Figure 3 shows the functional design of a three-layer laminate for medical footwear. The design was created so that it is easy to put it on and take off, and the aesthetic component as added value was not neglected. The models shown in Figure 3 are more demanding to produce than ordinary disposable covers. They have a tread to which the upper part of the cover is sewn, which is larger than the foot or shoe. To adhere better to the foot, they are fitted with Velcro strap so that they can be worn over shoes or on bare foot, as can be seen in the examples. Three design solutions of a three-layer laminate cover to be used for microbial protection are proposed in Figure 3.

Proposal a) can be easily pulled on and adjusted with the Velcro strap on the heel, while the excess material is folded forward, then covered with an accessory and secured with the Velcro strap. In example b), the heel is adjusted in the same way as in the previous model and the Velcro strap is fastened at the front to stand firmly around the foot. Similar to slippers, the model in example c) is only fixed on the side in the middle where the front and back are joined. In this way, it is more flexible and, as shown, can be easily adjusted and tightened with the Velcro strap. The proposed design is somewhat more expensive and demanding to produce, but since it is not a disposable product, it would be worthwhile to invest a little more at first. The models presented can be adapted according to needs and requirements, and it is proposed to produce them in two sizes to improve fit and therefore protection. This is also a good example of sustainability and environmental protection, as reusable covers also reduce waste, which is another added value.

4 Conclusion

This paper investigates the efficiency of the microbial barrier of textile PES/PU/PES laminate with respect to washing stability and the sterilization process. Bacterial spores of the genus *Geobacillus stearothermophilus and Bacillus atrophaeus* were used. The durability of the microbial barrier over a period of one, two and three months after 10 and 20 washing and sterilization procedures was determined for a three-layer textile laminate. The results showed that the sample had an effective microbial barrier through 20 washing and sterilization procedures. The durability of the microbial barrier tested over three months also showed that there was no penetration of microorganisms to the inside of the sterilized packaging. From this it can be concluded that the sample has an extremely effective microbial barrier and its durability is guaranteed after 10 and 20 washing and sterilization procedures, and after storage under strictly controlled conditions for a period of one, two and three months. The PU membrane between two polyester layers in the laminate has a major influence on this impermeable barrier. The value of retained microorganisms on the surface of the three-layer PES/PU/PES laminate was 3.8 times higher than the initial value. The process of washing and sterilizing samples often leads to their permanent shrinkage, and these changes cause a linear increase in mass and thickness.

A functional design of a three-layer laminate for medical footwear with emphasis on flexibility, practicality and wearing comfort was proposed. All three proposals meet both the functional and aesthetic value.

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