Functional Design and Construction of Reusable Surgical Gowns Considering Microbial Barrier

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ABSTRACT
The objective of this paper is to propose a functional design of surgical gowns regarding previously investigated properties of textile materials. The following materials were used for the surgical gowns: 100% Tencel, 50% PES/50% cotton and PES/PU/PES three-layered textile laminate. The materials showed satisfactory properties throughout 50 washing cycles and 50 sterilization cycles under realistic conditions at KBC Zagreb (University Hospital Centre Zagreb). Construction and modelling were carried out based on necessary requirements in the operating room. Functional design is proposed based on microbial barriers permeability and air permeability results.

KEYWORDS
Functional design, clothing construction, modelling, reusable surgical gowns, microbial barrier

INTRODUCTION
Surgical clothing is a class 2 medical textile, which is used for bacteria transfer reduction from the skin of surgical personnel into the air in the operating room, as well as for the protection of surgical personnel from contact with body fluids [1]. Protective clothing is defined as -“clothing which covers or replaces personal clothing and which are designed to provide protection against one or more hazards“ [2]. Disposable gowns are intended for use during the operation after which they are thrown away. However, reusable surgical gowns usually have to fulfil many more requirements and resist abrasion during use. Typical hospital environment, including operating rooms, presents multiple potential dangers for contamination of healthcare professionals and patients. Necessary protection is provided by using different types of clothing and textiles. Although there are many standards for determining performance of medical textiles, most tests are carried out in laboratory conditions and against one hazard only. When used, a surgical gown can consist of several layers, either as one product, or several products simultaneously worn as a set [3, 4]. The penetration of microorganisms will be smaller through several layers of the same fabric compared to one layer. Air permeability will be reduced by adding layers of the same fabric as well. For example, when using one or two layers of the same fabric, air permeability is reduced by approximately 50% and approximately 30% when using two or three layers , etc. [5].
The Disease Control Centre has proposed that surgical gowns and other medical textiles, disposable or reusable, must be impermeable to fluids and viruses [6]. The Nurses Association has proposed that fabrics used for surgical gowns must minimize penetration of bacteria from non-sterile to sterile areas and resist fluids transfer, abrasion and perforation [7]. The choice of fabric depends on the professional task and the degree of surgeon’s exposure, e.g. fluid-resistant surgical gowns are worn when there is a risk of contamination of the surgeon by passing of blood and other fluids [8].

Surgeon’s protective clothing must not allow blood or other body fluids to get onto or pass through surgical clothing under normal conditions of use. In addition, in reference to reusable surgical clothing, the duration of the protective function of the surgical gown material itself is important. [9, 10]. In 1978, the Association for the Advancement of Medical Instruments (AAMI) established four levels of protection, from the minimal AAMI Level 1 to the highest AAMI Level 4. AAMI Level 1 and Level 2 unreinforced surgical gowns are intended for low or moderate contact with fluid and short term surgery with minimal risk of contamination. AAMI Level 3 reinforced surgical gown is intended for moderate to high contact with fluid. AAMI Level 4 impenetrable surgical gown is intended for long operating procedures and high intensity contact [8]. The goal of the study was to propose a functional design of surgical gowns regarding previously investigated properties of textile materials. Construction and modelling were carried out based on necessary requirements in the operating room. Functional design is proposed based on microbial barriers permeability and air permeability results. Both comfort and 100% protection against penetration of microorganisms, blood and all body fluids was achieved with the combination of textile materials. As a result, the AAMI classification of surgical gowns requirement is fulfilled and a proposal for new models of reusable gowns is given (the term of validity of minimum 50 washing cycles and 50 sterilization cycles).

**EXPERIMENTAL**

**Materials and Methods**

In order to ensure the best protection from infections for the surgeon and the patient, it is important to select materials that have the appropriate microbial barrier. For functional surgical gown design, a combination of materials was used according to their characteristics. The basic characteristics of the material are shown in Table 1 [11].

| Textiles             | Composition (%) | Weave         | Surface area (g/m²) | Yarn count (tex) | Density (threads/cm) |   |
|----------------------|-----------------|---------------|---------------------|-----------------|---------------------|---|
|                      |                 |               |                     | Warp            | Weft                |   |
| PES/cotton           | 50/50           | Linen         | 178.6               | 28.60           | 42.28               | 34 |
| Tencel®              | 100             | Bluette 2/1   | 193.7               | 22.83           | 31.30               | 50 |
| PES/PU/PES Three-layer textile laminate | 216.0          | -             | -                   | -               | -                   | -  |

The goal was to achieve the necessary comfort and to allow unrestricted motion of the surgical staff. In addition to these two requirements, it was necessary to achieve the required microbial barrier in critical areas such as the front part and the sleeve. Functional design was carried out based on previously published medical textiles research. The research was conducted in collaboration with the University Hospital Centre Zagreb. The samples were exposed to 50 washing cycles and 50 sterilization cycles under actual hospital conditions after which microbial barrier permeability and air permeability tests were performed.

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RESULTS AND DISCUSSIONS

Based on the microbial barrier permeability and air permeability results, functional design and modelling of reusable surgical gowns was carried out [11]. According to the air permeability results, Tencel® achieved air permeability maximum and therefore maximum comfort [11]. Tencel® is a man-made cellulosic fibre of the generic fibre type lyocell. It has the ability to absorb water and moisture into its nanostructure, which reduces the tendency of microorganisms growth. The high absorption capacity provides the necessary comfort. An even greater advantage is given to Tencel® from a medical aspect because it does not release particles or produces textile dust [12, 13].

PES/PU/PES three-layered textile laminate meets the European standards for surgical textiles EN 13795; it is impermeable to all liquids, viruses and also meets dry and wet microbiological tests. Therefore, laminate is used in the above mentioned models where maximum protection against fluid spraying is needed and because of the possibility of microbial contamination.

The air permeability \( [R] \) of tested samples was measured in compliance with EN ISO 9237, Figure 1. The results show that Tencel® has the best air permeability, while the PES/PU/PES three-layered laminate is completely air impermeable throughout all 50 wash and sterilization cycles [11].

![Figure 1. Air permeability of the tested medical textiles (W+S - washing and sterilization, R - air permeability)](image1)

The results of medical cellulosic textiles permeability of microorganisms after extreme conditions of contamination with bacterial spores are shown in Figure 2 [11].

![Figure 2. The number of biological colonies on the back side (CFU - Colony Forming Unit)](image2)
The results show that the PES/PU/PES three-layered laminate is impermeable to microorganisms and has an excellent microbial barrier, while Tencel® showed better microbial barrier than PES/cotton [11]. Raglan sleeve model that provides the necessary freedom of motion and comfort for the surgeon was used on all models. The combinations of textile materials were used in order to meet the AAMI classification of surgical gowns from Level 1 to Level 4. The functional design is shown in Figure 3.

Surgical gown models that are used for simpler surgical procedures which are less time-consuming and without any risk of microbial contamination are made of Tencel® because of the satisfactory microbial barrier in dry state and the comfort it provides. Where a microbial barrier and protection against spraying of blood and other body fluids are required, a functional design of the model is proposed using a combination of two textile materials.

PES/PU/PES three-layered textile laminate is applied on the front part and on the sleeves where there is a great potential for contamination with microorganisms and where protection from fluids permeability is required. Tencel® is proposed for the back part in order to achieve greater comfort for the surgeon. The construction was carried out based on literature [14]. Construction and modelling are shown in Figures 4 and 5.
CONCLUSIONS

The functional design presented in this paper is proposed based on results obtained after use in actual hospital conditions. Textile materials used have appropriate properties during 50 washing cycles and 50 sterilization cycles. The necessary comfort and freedom of motion are achieved using raglan sleeves. In the Tencel® and the PES/PU/PES three-layered textile laminate combination, Tencel provides comfort and the textile laminate provides 100% protection against penetration of microorganisms, blood and all body fluids. In this way, the AAMI requirements for the classification of surgical gowns are fulfilled and a proposal for new models of reusable gowns is given.
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