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ORIGINAL ARTICLE

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The influence of the sterilisation process on certain thermal properties

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Abstract Surgical clothing and sheets have to meet all the requirements set in the health-care industry regarding body comfort, absorption capacity and general recognition of physiological safety and sterilisation capacity. The disposable surgical gown market is growing and the demand will increase in all product groups and market sectors, where the health care industry is the most dynamic growth area. The aim of this study was to analyse some of the thermal properties of disposable surgical gowns before and after different sterilisation methods, and therefore the influence of the sterilisation process on their thermal comfort. The apparatus used to measure heat transfer properties was the Thermo Labo device (KES FB7) which evaluates the cool/warm sensation, thermal conductivity and insulation properties of the test item. The results obtained highlight the influence of the sterilisation process on the thermal and comfort properties.

Keywords Textile · Comfort · Sterilisation · Heat transfer

Introduction

Many people have to work in environments which expose them to specific risks from which they need protection. All clothing is protective to some extent, but it is the degree of protection required from a specific risk that determines the type of protective clothing necessary. Unfortunately, the comfort of use, the interaction with the body, and the fabric properties are mostly forgotten in the selection of textiles for protective clothing.

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Many properties related to comfort can be objectively measured. The objective factors considered in the assessment of comfort are usually the thermal and moisture properties, and the fabric and fibre characteristics.

The study was carried out upon the thermal properties of a specific protective garment: the single-use surgical gown. The European Economic Community directive 93/42/EEC on medical devices is the European basis for evaluating surgical materials. A proposed mandatory European standard, prEn 13795 "Surgical drapes, gowns and clean air suits used as medical devices, for patients, clinical staff and equipment", is being developed by the Committee of European Normalisation CEN TC 205 WG 14 and specifies the basic performance requirements and test methods for single-use and reusable materials. These requirements must also be fulfilled after the sterilisation process, underlying the importance of this study for the development of this European standard (CEN 2001).

Unfortunately, these performance requirements are mainly focused on the mechanical and sterilisation aspects. Four methods of sterilisation are in common use today: gas, irradiation, steam autoclave and dry heat. The former two are also called low temperature sterilisation methods, and are applied to single-use products, while the latter two, the high temperature sterilisation methods, are applied to reusable products. (Araujo Marques 1997). Up until now, the comfort aspect has not been taken into account in the performance standards (Lutolf 1999). Therefore, in order to characterise the comfort aspect, several methods classically used in the textile field for the evaluation of the thermal properties of fabrics (Shishoo 1988; Schacher et al. 2000) have been performed here.

Materials and methods

The samples studied were processed using an industrial sterilisation line with the chosen irradiation method being either 0, 80, or160 kGy, since this dose range covers the conditions for the industrial sterilisation process (25 kGy).

Three different types of basic materials were used for the surgical gowns: nonwoven (45% polyester, 55% cellulose), laminate (first layer: 20 g low density polyethylene (LDPE) film; second layer: nonwoven 70% viscose, 30% polyester) and a polyethylene (PE). All gowns were irradiated under the conditions described in Table 1.

The apparatus used to measure the heat transfer properties was the Thermo Labo I device (Kawabata 1991), which evaluates both the heat absorption and the thermal conductivity. All surfaces are made of materials that conduct heat at varying rates—thermal conductivity. Our thermal sensations are not reliable indicators of surface temperatures, but we sense the rate of heat loss or gain.

Heat absorption

The greater the Q_{max} value is, the greater the sensation of coolness to touch. When a pre-heated hot plate (as a simulator of human skin) is placed on a fabric sample, a heat flux versus time curve is generated (Fig. 1). Maximum peak flux is Q_{max} measured 200 ms after the hot plate contacts the fabric, a time that approximates the cool/warm feeling experienced when a fabric is placed on the skin. Because Q_{max} is influenced by a combination of the fabric surface and its thermal properties, it can be expected to be an important predictor of the cool/warm sensation experienced after skin-to-fabric contact.

Table 1 Thickness of the irradiated materials

Radiation dose (kGy)		Thickness (mm)		
		Laminate	Nonwoven	PE
β	0	0.167	0.378	0.126
	80	0.265	0.471	0.151
	160	0.281	0.471	0.136
γ	0	0.167	0.378	0.126
	80	0.270	0.466	0.137
	160	0.238	0.478	0.172

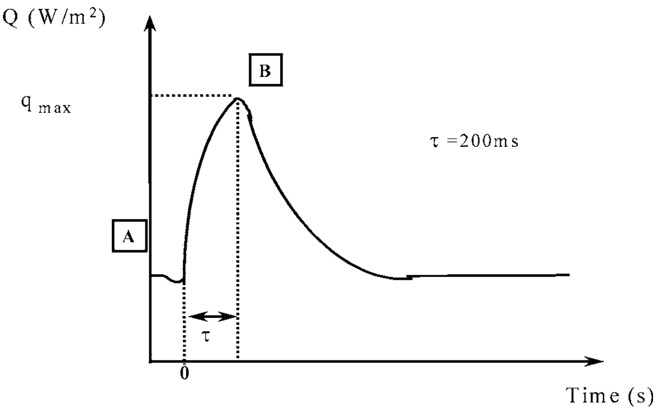

Fig. 1 Cool/warm sensation measurement

Thermal conductivity

The equipment used evaluates the thermal conductivity (*K*), measuring the heat flow loss (*W*) and taking in consideration the thickness of the sample, the area of the heated plate (skin) and the temperature difference between the "skin" and the test environment according to the equation:

$$K = \frac{W \times D}{A \times \Delta T} \times 10^2 (W/m^\circ \mathrm{K})$$

D represents the thickness of sample (cm), *A* represents the area of the guarded hot plate (cm^2), and ΔT represents the temperature difference between the fabric and the environment (°K). Different simulated skin-clothing models were used including simulation of dry, wet and wet/space and air velocity conditions and configurations.

For the dry skin model, a guarded hot plate was used as a heat source and the specimen was placed on it. For the wet skin model, a wet paper was placed between the guarded hot plate and the specimen. For the model that simulated skin with no contact between the garment and the skin of the wearer, a 0.5 cm air space was maintained between the specimen and the hot plate. Two different air velocities were chosen: 30 cm/s and 100 cm/s.

Ten separate samples (10×10 cm) cut from each material were used. Values reported are the average of the ten determinations. Both sides of the tested materials have been tested.

Results

The cool/warm sensation and the thermal conductivity before and after sterilisation with the different doses of irradiation under the different configurations were measured, and the influences of the air conditions (temperature, humidity, air movement) on the thermal insulation were investigated.

Comparison of the results of the cool/warm sensation tests for the untreated samples and the irradiated samples are presented in Figs. 2, 3 and 4 for the nonwoven, laminate and PE, using the legend described in Table 2. The results of the the thermal conductivity assesments for the three sample types are presented in Figs. 5, 6 and 7, using the legend in Table 3. The results of the tests of the influence of air conditions (temperature, humidity, air movement) on the thermal insulation properties of the nonwoven, laminate and PE samples, either untreated or after irradiation, are presented in Figs. 8, 9, 10, 11, 12 and 13, with the legend given in Table 4).

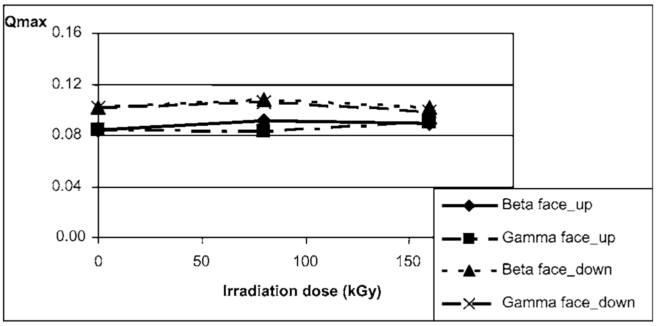

Fig. 2 Influence of the radiation dose on cool/warm sensation for the nonwoven material

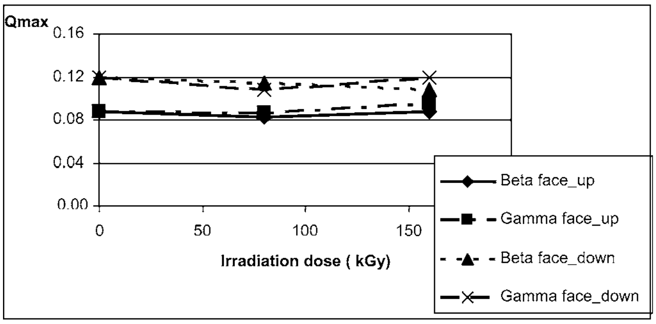

Fig. 3 Influence of the radiation dose on cool/warm sensation for the laminate

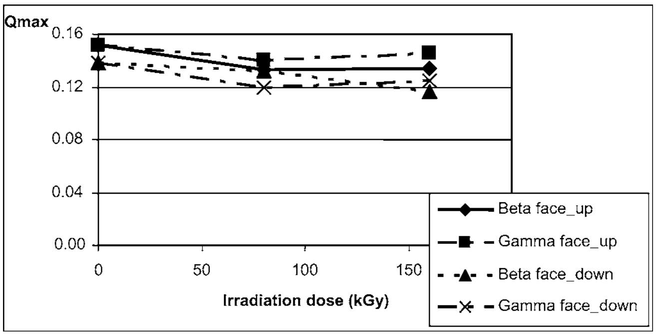

Fig. 4 Influence of the radiation dose on cool/warm sensation for the polyethylene

Table 2 Legends to Figs. 2, 3 and 4

Type of irradiation	Type of face	Legend
β	Up	–♦–
β	Down	–▲–
γ	Up	–■–
γ	Down	–X–

Discussion

We have selected three different materials used for the production of single-use surgical gowns and subjected

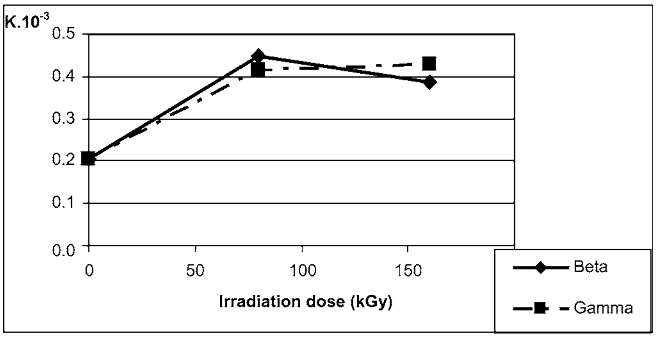

Fig. 5 Influence of the radiation dose on the thermal conductivity for the nonwoven material

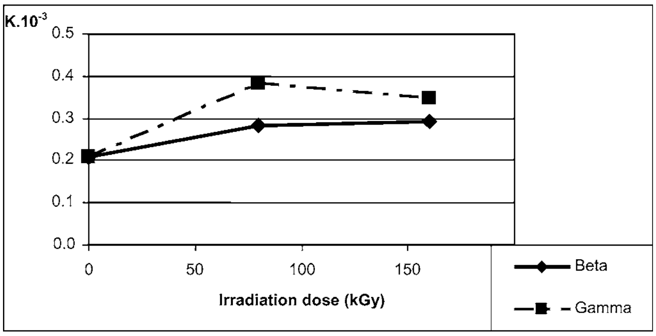

Fig. 6 Influence of the radiation dose on the thermal conductivity for the laminate

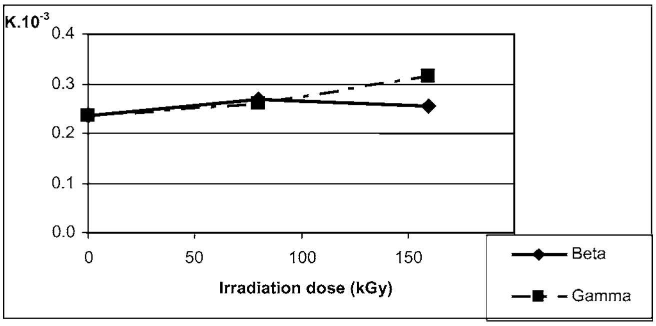

Fig. 7 Influence of the radiation dose on the thermal conductivity for the polyethylene

Table 3 The legend of Figs. 5, 6 and 7

Type of irradiation	Legend
β	–♦–
γ	–■–

them to a range of sterilisation protocols using different doses of radiation for each material and for each configuration to determine the effect of the sterilisation method on the thermal properties of these materials. The statistical significance of the test results were analysed using a test of the variance (F-Snedecor Fisher), a test of

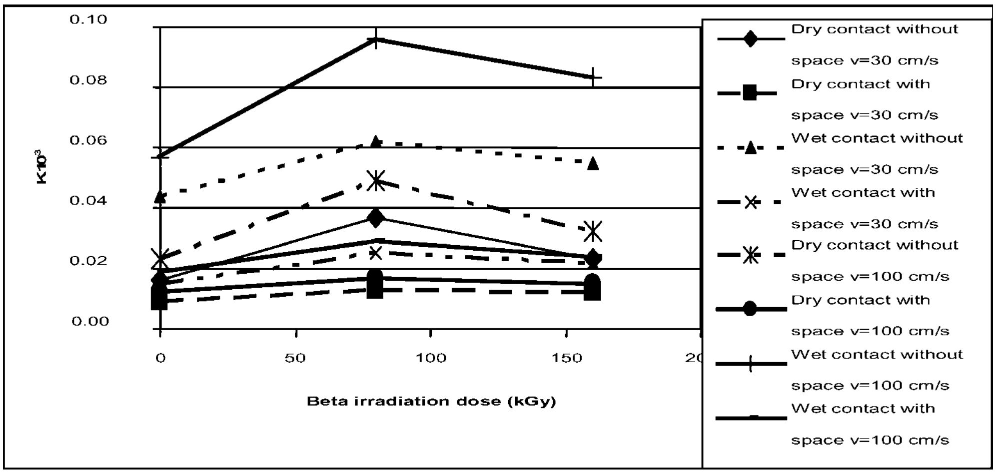

Fig. 8 The influence of air conditions on the thermal insulation capacity of the nonwoven fabric irradiated with β-irradiation

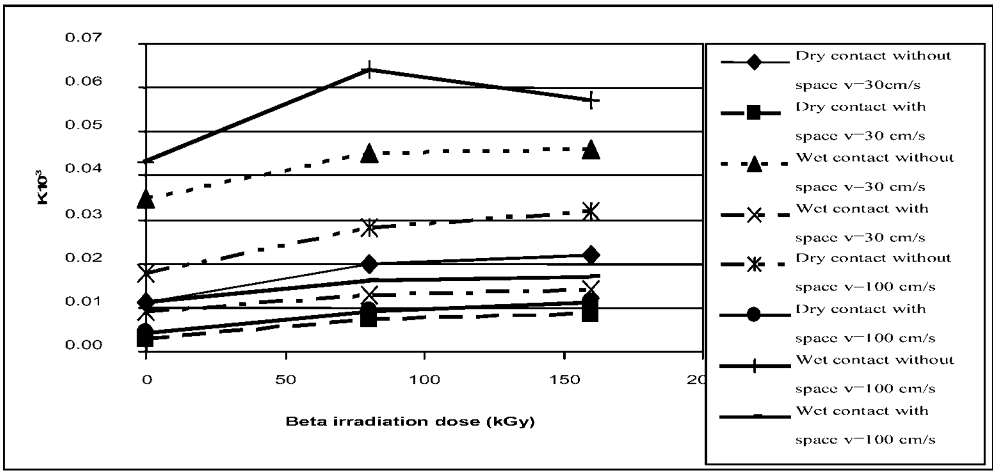

Fig. 9 The influence of air conditions on the thermal insulation capacity of the laminate irradiated with β-irradiation

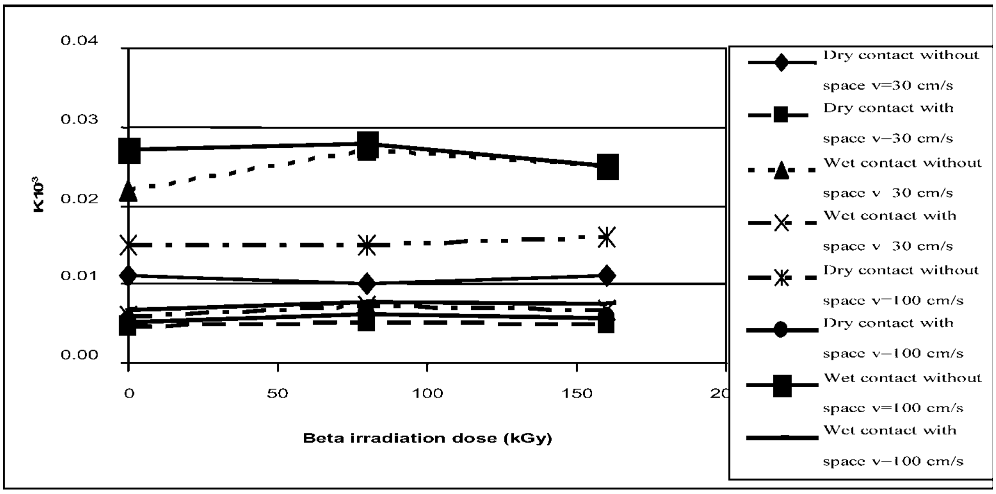

Fig. 10 The influence of air conditions on the thermal insulation capacity of polyethylene irradiated with β-irradiation

the means (t-Student Fisher) and an analysis of variance using non-irradiated material as reference.

For laminate, the face tested was the most important factor in terms of the Q_{max} value, rather than the dose or type of irradiation used for sterilisation. However, in terms of the K value, the type and the dose of radiation were important (γ-irradiation was more aggressive than β-irradiation), and a dose of 80 kGy seems to be the critical threshold from which the thermal properties of the laminate were modified.

For the nonwoven material, the same tendency as was seen for the laminate was observed with respect to the

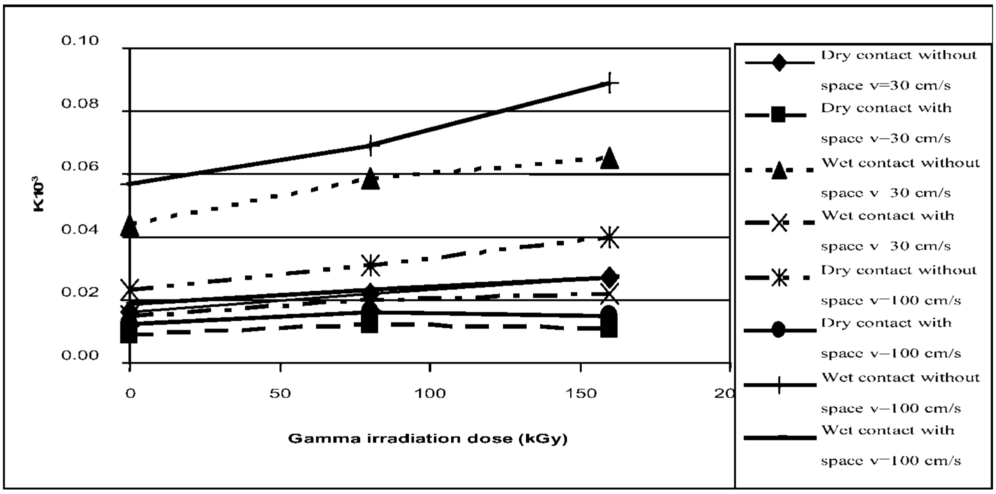

Fig. 11 The influence of air conditions on the thermal insulation capacity for the nonwoven fabric irradiated with γ-irradiation

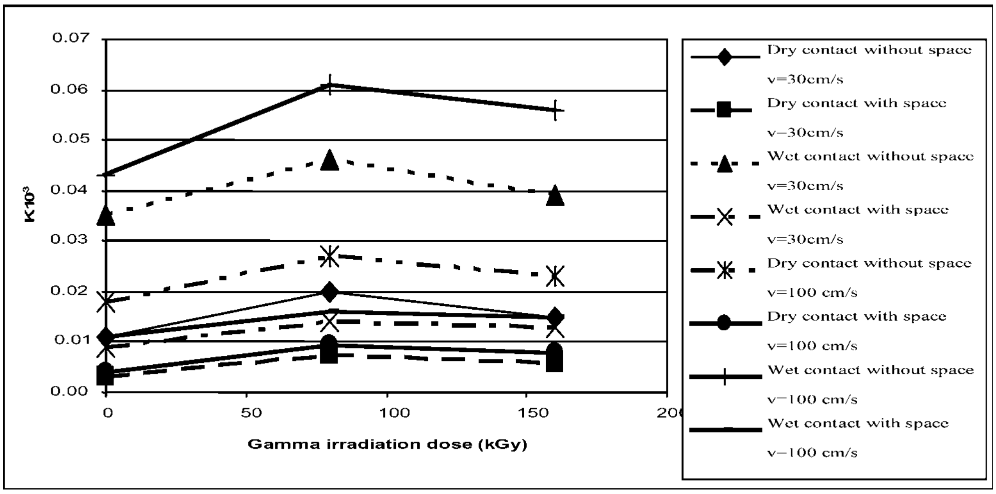

Fig. 12 The influence of air conditions on the thermal insulation capacity of the laminate irradiated with γ-irradiation

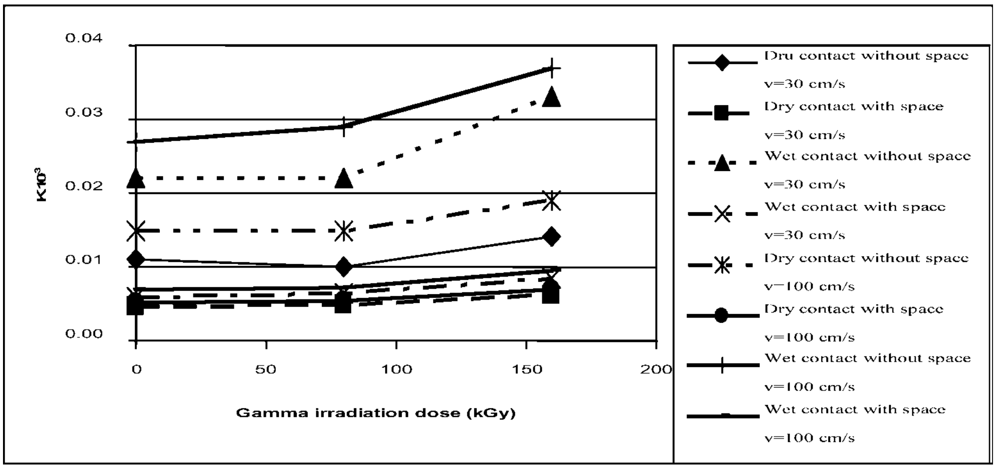

Fig. 13 The influence of air conditions on the thermal insulation capacity of polyethylene irradiated with γ-irradiation

influence of the radiation dose on the Q_{max} value. Once again, the K value was strongly affected by the radiation dose and a dose of 80 kGy was also a threshold for the behaviour of this parameter.

For the PE material the faces seem less differentiated in terms of their effect on the Q_{max} value, but the dose of 80 kGy remains a critical point. Again, in terms of their effects on the K value, γ-irradiation seemed to be more aggressive than β-irradiation, whose effects stabilised above a dose of 80 kGy.

Concerning the influence of the air conditions (temperature, humidity, and air movement) on the thermal insulation properties of the different materials, for all three fabrics K increased with increasing air speed, and

Table 4 The legend of Figs. 8, 9, 10, 11, 12 and 13

Velocity (cm/s)	Type of contact	Space	Legend
30	Dry	Without	–♦–
		With	–▮–
	Wet	Without	–▲–
		With	–X–
100	Dry	Without	–X–
		With	–●–
	Wet	Without	–+–
		With	–■–

this effect is more important in the case of wet rather than dry contact. In contrast, K decreased when the space between the fabric and the hot plate was increased.

To summarize, in the case of the nonwoven material, the heat absorption capacity showed a significant difference for both ionizing radiation processes at all dose values, except for gamma irradiation at a dose of 160 kGy (face down). For thermal conductivity, there are significant differences at all irradiation doses. In the case of the laminate material, for both properties studied (heat absorption and thermal conductivity) a significant difference was seen at all doses with both types of radiation. In the case of polyethylene, the heat absorption and thermal conductivity values show significant differences for all dose values.

Conclusion

These studies have highlighted the fact that the disposable materials used in the hospital sector (laminate, nonwoven, PE) are affected by the sterilisation process. This impact varies as a function of the type of radiation and the dose applied; and is more important for γ- versus β-irradiation, with a threshold value around 80 kGy. These modifications are due to polymer degradation, and further studies in this direction are under way. Regarding the comfort properties, both types of radiation modified the general thermal behaviour of the tested products. Increased doses drive the insulation property down, and increase the cool/warm sensation (warmer sensation). Taken together, these results highlight the fact that γ-irradiation is more aggressive by comparison with β-irradiation.

References

Araújo Marques MJ (1997) Contribuição para a definição de propriedades de materiais têxteis hospitalares descartáveis. Dissertation, University of Minho

CEN/TC 205/WG 14 prEN 13795 (2001) Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical staff and equipment, part 1: general requirements for manufacturers, processors and products.

Kawabata S (1981) The standardisation and analysis of hand evaluation. The hand evaluation and standardisation committee, Textile Machinery Society of Japan, Osaka

Lutolf HP (1999) Wear and laboratory testing OR gowns comfort properties of spunlace nonwovens versus cotton woven fabrics. Index 99 Congress, April 1999, Geneva

Schacher L, Adolphe DC, Drean JY (2000) Comparison between thermal insulation and thermal properties of classical and microfibre polyester fabrics. Clothing Sci Technol 12:84–89

Shishoo RL (1988) Technology for comfort. Textile Asia, June 1998