

New requirements for surgical gowns as protective clothing for the medical staff and for the patients

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1. INTRODUCTION

In the EU Member States, over 30 million clinical operations are performed every year with an increasing tendency. Between 5% and 10% of them are accompanied by hospital infections, 5% of which develop dramatically, eventually leading to around 50.000 additional fatalities per year in Europe. 25% of all post-operative infections are caused by wound infections in operational theatres. Contaminated particles are a frequent cause of infection, by contact or airborne, between surgeon team and patient and/or across the patient surface.

The transference of pathogens through body fluids has received much attention, especially in the last twenty years. The use of protective surgical apparel is essential to create a barrier to microbial transfer.

Bacteria are believed to be transported from one location to another by carriers such as dust or liquids. In the operating theatre, fluids such as blood, perspiration and alcohol act as carriers transporting the bacteria through the fabric. Small particles such as skin cells and lint also may act as carriers. Therefore one must consider the barrier fabric's effectiveness in preventing transmission of the carrier and of the bacteria (Leonas and Junkins, 1997)

Surgical gowns and drapes are used to minimize the spread of infective agents to and from patients' operating wounds, thereby helping to prevent post-operative wound infections. The use of surgical gowns with resistance to the penetration of liquids can also diminish the risk to the operating staff from infective agents carried in blood or body fluids.

Microbial exchange is supported by surgical drapes and gowns with inadequate barrier functions, made of either reusable or disposable materials.

2. EVOLUTION OF THE EUROPEAN STANDARDS RELATED TO SURGICAL GOWNS

Surgical gowns are protective clothing that in fact have a double effect of protection: protection of the clinical staff and protection of the patient. The rapid increase of diseases like AIDS has led to a higher awareness and concern of the importance of the use of adequate high performance surgical gowns.

Within CEN (European Committee for Standardization) the Technical Committee CEN/TC205, which deals with "Non-active medical devices" has a specific working group WG14 "Surgical clothing and drapes, and medical face masks" which has been developing, since the 1990's, technical specifications and test methods for surgical gowns and drapes, important to define the conditions required to implement the EU Directive 93/42/EC of 14th June 1993 (and the amendments made by the EU Directive 2007/47/EC of 7th September) which specifies the characteristics that medical devices must fulfil.

The last version of the European Standard EN13795 has been published in 2011. This standard is essential for the implementation of the EU Directive 93/72/42 and also to the compulsory use of the CE mark. This standard is at present already in revision, due to the updating of one of the important test methods used to evaluate the wet penetration (ISO 22610). This is important with regard to the requirement 'resistance to microbial penetration – wet', especially in critical areas of standard performance surgical gowns and drapes. At present, a lot of discussion is being held within WG14, especially between the producers of disposable surgical gowns and suppliers of reusable gowns.

3. MATERIALS AND METHODS; CASE STUDY

In the market there are two types of surgical protection materials: disposable and reusable, both fulfilling the requirements of EN 13795 2011. Disposable gowns are normally made in non woven materials which assure an efficient protection. These materials are expensive and have a significant impact on the environment, as they are normally incinerated after use.

In the present work, new generation textile surgical protection materials have been tested. The materials that have been used for the manufacturing of the gowns were based on trilaminated textiles, including a membrane with micro pores which assures a barrier effect against microorganisms, with a certain comfort for the medical staff. In fact, this membrane is absolutely waterproof but has a certain water vapour permeability, important for the passage of perspiration of the medical staff. These materials allow a multiple use, but are only economically attractive if they can stand a high number of washing/disinfection, drying and sterilizing cycles.

The present work includes real tests with the reusable gowns in the operation theatre, hospital laundry and sterilization, with control of the evolution of the properties of the material during forty reusing cycles. The tests have involved a total of 1445 orthopaedic surgeries. Some of the tests required by EN 13795 have been performed on the gowns, to check the fulfilment of the required levels after the successive using, washing/disinfection, drying and sterilizing cycles. Tests

included bursting resistance, delaminating force, water permeability, water vapour permeability, linting and bacteriological barrier.

A survey of the opinion of the surgical team about these materials has also been made. The environmental impact of reusable surgical gowns during their life cycle has been made, including the washing/disinfection, drying and sterilizing processes, in comparison with disposable gowns.

4. RESULTS AND DISCUSSION

Results from the case study show that even after forty reusing cycles, the reusable gowns have still good protection properties. The values in terms of mechanical resistance and water permeability are still much higher than the present requirements of EN 13795. The enquiry made to the medical staff (surgeons, anaesthesiologists, nurses, etc.) show also a good acceptance of the reusable gowns.

5. CONCLUSIONS

Surgical gowns are essential to prevent direct contact transfer of potentially infective agents from the surgical team to the operating wound and vice versa. The requirements for the materials specified in the EN 13795 standard can be fulfilled both by disposable and by reusable gowns of new generation.

A cost-benefit analysis carried out on the basis of real tests in a hospital show that there is an advantage for reusable materials, which is in agreement with other results published in the literature (e. g. Baykasoglu, 2009). Performance levels of the reusable surgical gowns, even after several reusing cycles, are higher than the disposable gowns. The cost and the environmental impact are lower.

6. ACKNOWLEDGMENTS

The authors would like to acknowledge the supplier of the reusable gowns, the garment manufacturer, the Hospital where the surgeries have been carried out and the laundry.

7. REFERENCES

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