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EXPERIMENTAL EVALUATION OF THE QUALITY AND STABILITY OF STERILE SURGICAL GOWNS MADE OF NONWOVEN MATERIAL

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Abstract

The results of testing sterile surgical gowns made of domestically produced SMS nonwoven material are presented. For each standardized quality parameter, a quality safety margin coefficient was calculated, which made it possible to identify the indicators requiring priority control. It was shown that sterility testing of 84 samples can only rule out contamination levels above 3.5%; therefore, sterility assurance must be provided through validation of the sterilization process. Based on data from 36 months of storage, it was established that shelf life is limited by the strength of the package heat-sealed seam.

Keywords: Nonwoven material, surgical gown, sterility, quality safety margin coefficient, process capability index, heat-sealed seam, shelf life.

Introduction

SMS-type nonwoven materials (spunbond–meltblown–spunbond) have become the principal raw material for disposable surgical gowns due to the combination of the mechanical strength of the outer layers and the barrier properties of the



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inner layer composed of ultrafine fibres [1]. In national practice, gowns are accepted in accordance with GOST 12.4.280-2014 and UzTR.148-008:2016, whereas indicators directly characterising the medical performance of the product are controlled selectively. The aim of this study was to establish an experimental basis for a quality assessment system for such products: to determine which indicators have the smallest safety margin relative to the specified limits, to interpret the results of sterility testing, and to identify the parameter that limits shelf life. This study continues previously initiated research on the quality indicators of surgical gowns [6].

Materials and Methods

The study included gowns with a basis weight of 35 g/m², sterilised with ethylene oxide, obtained from 12 batches produced by two enterprises. Physical-mechanical and hygienic properties were determined in accordance with GOST 3811-72, GOST 3813-72, GOST 3816-81, and GOST ISO 9237-2013, while electrophysical properties were assessed according to GOST 32995-2014 and GOST 19616-74. Sterility of 84 gowns was tested in accordance with ISO 11737-2 [2], cytotoxicity was evaluated using L929 cells in accordance with ISO 10993-5, and package heat-seal strength was measured according to ASTM F88.

Stability was assessed by accelerated ageing at 40 °C in accordance with ASTM F1980 and by storing 48 samples under normal conditions for 36 months. For each parameter, a quality safety margin coefficient was calculated as the ratio of the measured value to the specified requirement; for parameters with a “not more than” criterion, the inverse ratio was used.



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Results and Discussion

All standardized parameters of the surgical gown met the specified requirements; however, their safety margins relative to the applicable limits differed by more than one order of magnitude (Fig. 1).

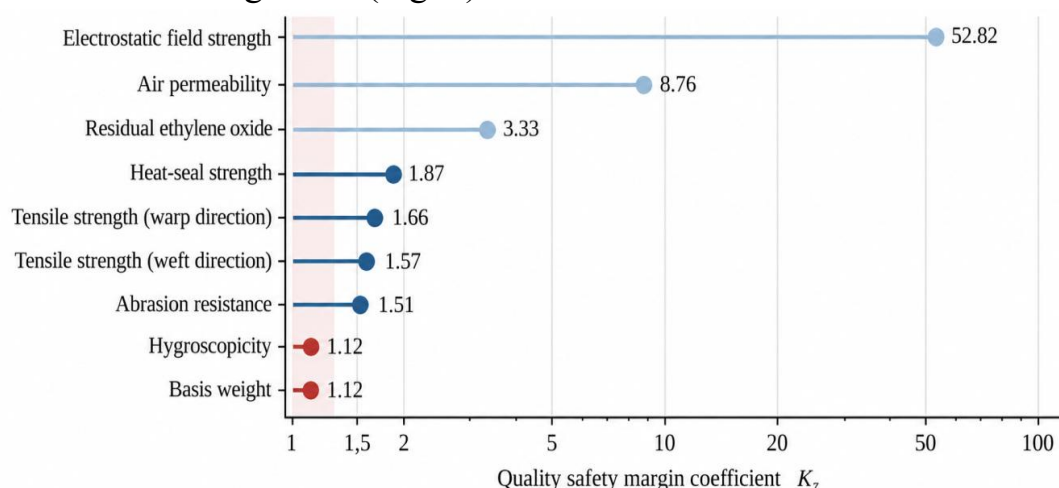


Figure 1. Quality safety margin coefficients for the parameters of a sterile surgical gown (logarithmic scale)

The parameters were clearly divided into three groups. For air permeability and electrophysical characteristics, the measured values were 9–53 times better than the specified limits. These limits were originally established for household clothing and therefore are not restrictive for surgical gowns. The safety margin for the mechanical properties ranged from 1.51 to 1.87. The minimum margin, 1.12, was observed for basis weight and hygroscopicity.

Calculations based on three validation batches showed that the process capability index for hygroscopicity was only $(C_{pk}=1.00)$, whereas for basis weight it was 2.33. For requirements of the “not less than” type, the relationship between these characteristics is expressed as



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$$C_{pk} = \frac{1 - 1/K_z}{3 \cdot CV}, \quad (1)$$

where CV is the coefficient of variation of the parameter. Accordingly, the condition $C_{pk} > 1.33$ leads to the requirement

$$K_z \geq \frac{1}{1 - 4 \cdot CV} \quad (2)$$

At $CV = 0.036$, a safety margin of at least 1.17 is required, whereas the actual value was 1.12. Therefore, hygroscopicity and basis weight should be monitored in every batch of roll material.

Of the 84 gowns tested, no microbial growth was detected in 83 samples, while one sample yielded a positive result. It is important to interpret this result correctly. If no growth is observed in any of n samples, the upper 95% confidence limit for the proportion of contaminated products is

$$1 - 0.05^{1/n} \quad (3)$$

For $n = 84$, this value is approximately 3.5%, whereas confirmation of a contamination level of 0.1% would require approximately 3,000 samples. A sterility assurance level of $SAL = 10^{-6}$ cannot, in principle, be demonstrated by sample testing alone and can only be ensured through validation and routine control of the sterilization process [3,4]. Analysis of sterilization-cycle parameters showed that the single nonconformity was associated with a decrease in relative humidity during preconditioning, namely 53.8% compared with the nominal value of 55%, indicating humidity as a key process parameter requiring control.

The material showed no cytotoxic effect: the proportion of viable L929 cells at an extract concentration of 0.2 g/mL was 95.9–97.4%, compared with the minimum requirement of 70%. The bacterial filtration efficiency of the gown was $98.4 \pm 0.8\%$, and all seven types of nonwoven products tested prevented



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penetration by bacteriophage Phi-X174, which is consistent with published data on the advantages of disposable products [5].

The heat-seal strength of the package ($n=84$) was 2.80 ± 0.40 N/15 mm, within the specified range of 1.5–4.0 N/15 mm. All samples complied with the requirement; however, the mean value was displaced from the midpoint of the specification range, and $C_{pk}=1.00$. Changes in the parameters during storage are presented in Table 1 and Fig. 2.

Таблица 1. Изменение показателей халата за 36 месяцев хранения ($n = 48$)

Показатель	0 мес.	12 мес.	24 мес.	36 мес.	Δ , %
Разрывная нагрузка по основе, Н	49,91	49,52	48,74	48,12	–3,6
Гигроскопичность, %	5,6	5,7	5,8	5,9	+5,4
Прочность сварного шва, Н/15 мм	2,8	2,7	2,5	2,4	–14,3
Остаток оксида этилена, мкг/дм ²	1,2	0,9	0,8	0,7	–41,7
Стерильность	роста нет	роста нет	роста нет	роста нет	–

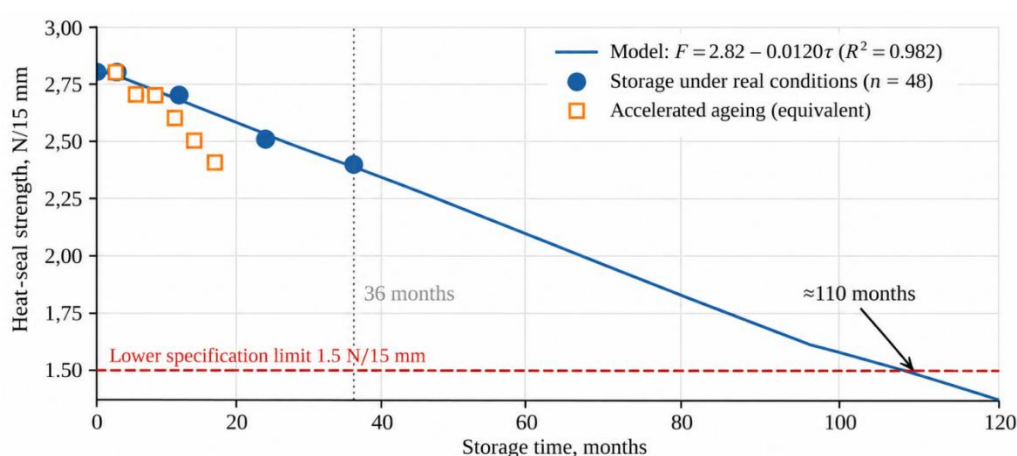


Figure 2. Package heat-seal strength during storage and extrapolation of the linear model to the specification limit.



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The greatest relative change was observed in package heat-seal strength (−14.3%). The linear model ($R^2 = 0.982$) reaches the lower specification limit after approximately 110 months, indicating that the established three-year shelf life has an almost threefold safety margin. Accelerated ageing produced a slightly more conservative estimate than storage under real-time conditions, supporting its suitability for shelf-life justification. Among the external factors examined, ultraviolet radiation caused the greatest reduction in material strength (−9.3% after 168 h); therefore, the products should preferably be stored in opaque secondary packaging.

Conclusions

1. The quality safety margin coefficient makes it possible to rank quality parameters according to the risk of nonconformity. For the SMS surgical gown, the limiting parameters are basis weight and hygroscopicity ($K_z=1.12$); for hygroscopicity, the target value should be increased to 5.8%.
2. Sample-based sterility testing confirms only the absence of gross contamination (not exceeding 3.5% at $n = 84$); sterility assurance should therefore be achieved through process validation with control of preconditioning humidity.
3. The shelf life of the sterile surgical gown is limited by the heat-seal strength of the package. Under the existing manufacturing technology, the established shelf life can be justified with an almost threefold safety margin.

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