

Experimental Quality Assessment Of Sterile Nonwoven Surgical Gowns And Verification Of A Two-Stage Acceptance Method

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ABSTRACT

The paper presents experimental results for a single-use surgical gown made of SMS nonwoven fabric and sterilised with ethylene oxide. Physical-mechanical, biological, barrier and package-integrity indicators were measured. Priority control indicators were identified from the relation between the quality margin coefficient and the process capability index. The sterility test result and the sterility assurance level were interpreted separately, and resistance to 36-month storage and to external influences was assessed. A two-stage acceptance method, in which mandatory safety requirements are checked before the integral quality index is calculated, was verified on production lots.

Keywords: nonwoven fabric, sterile surgical gown, quality margin coefficient, process capability, sterility assurance level, integral quality index, acceptance decision.

INTRODUCTION

Sterile surgical gowns made of nonwoven fabric act as the main protective barrier between medical staff and the patient. In Uzbekistan such products are in practice tested against GOST 12.4.280-2014 and UzTR.148-008:2016, which were developed for special protective clothing and light-industry goods. These documents do not cover sterility, biological safety or package integrity, and each indicator is compared with its limit separately, without regard to its importance. As a result, a lot whose physical-mechanical indicators all meet the limits but whose sterility is not assured may still be declared “conforming” [1, 2].

Earlier work proposed a two-stage assessment method that checks mandatory safety requirements separately from the overall quality rating, together with an integral quality index based on the “weakest link” principle [1]. The aim of this study is to determine the gown’s quality indicators experimentally, to examine the relations between them, and to verify on real production lots how well the proposed method supports acceptance decisions.

Object and methods. The object of the study is a single-use surgical gown made of polypropylene SMS fabric with a mass per unit area of about 35 g/m² and sterilised with ethylene oxide (EO). The main sample comprised 84 gowns taken from 12 lots produced by two manufacturers. Physical-mechanical, hygienic and electrophysical indicators were measured in an accredited laboratory according to GOST 3811-72, GOST 3813-72, GOST 3816-81, GOST ISO 9237-2013, GOST 32995-2014 and GOST 19616-74; sterility according to ISO 11737-2; cytotoxicity according to ISO 10993-5; and seal strength of the package according to ASTM F88.

Accelerated ageing was performed according to ASTM F1980 at 40 °C and 75% relative humidity for 6 months, and real-time storage lasted 36 months [3, 4]. Conformity decisions took measurement uncertainty into account using the ILAC-G8 decision rule [5].

For each indicator the quality margin coefficient was calculated as $K_z = P/Plim$ (for “not less than” requirements) or $K_z = Plim/P$ (for “not more than” requirements). The relation between the process capability index C_{pk} and K_z was derived as:

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

where CV is the coefficient of variation of the indicator. From (1), the minimum quality margin needed to satisfy $C_{pk} \geq 1.33$ is $K_{z,min} = 1/(1 - 4 \cdot CV)$.

Results And Discussion

The gown met the current requirements for all indicators that have established limits. The quality margin coefficients divided the indicators into three groups: the electrophysical indicators and air permeability exceed their limits by a factor of 9 to 53 or more; the mechanical indicators have an adequate margin ($K_z = 1.51$ – 1.66); and mass per unit area and hygroscopicity are closest to their limits ($K_z = 1.12$). Process capability calculations for three validation lots are given in Table 1.

Table 1
Quality margin and process capability of the main gown indicators

Indicator	Limit	Mean $\pm s$	K_z	$K_{z,min}$	C_{pk}
Breaking force (lengthwise), N	≥ 30	49.90 ± 0.48	1.66	1.04	13.82
Mass per unit area, g/m ²	≤ 40	35.8 ± 0.6	1.12	1.07	2.33
Hygroscopicity, %	≥ 5	5.6 ± 0.2	1.12	1.17	1.00
Package seal strength, N/15 mm	1.5–4.0	2.80 ± 0.40	–	–	1.00
EO residue, $\mu\text{g}/\text{dm}^2$	≤ 4	1.20 ± 0.10	3.33	–	9.33

As the table shows, the actual quality margin for hygroscopicity (1.12) is below the value required for a stable process (1.17), which gives $C_{pk} = 1.00$. This means the requirement is met only at the borderline, and about 0.13% of products may have hygroscopicity below the limit. To stabilise the process, mean hygroscopicity must be raised to at least 5.8% or lot-to-lot variation must be reduced. Because polypropylene fibres absorb no more than 0.1% moisture on their own, the fabric's hygroscopicity depends mainly on the quality of surface finishing; this indicator should therefore be controlled for each roll lot at incoming inspection.

Package seal strength in 84 samples followed a normal distribution (Shapiro–Wilk $W = 0.989$; $p = 0.712$), and all values were within the specified range. However, because of the large spread ($CV = 14.3\%$), C_{pk} was 1.00, and about one seal in 520 is expected to fall outside the limits. Since the mean is close to the centre of the range, the process does not need re-centring; instead its variation should be reduced by tighter control of sealing temperature and pressure.

EO sterilisation (60 °C, 5 h) changed the elastic modulus and tensile strength of polypropylene, high-density polyethylene and flash-spun polyethylene by less than 1%. The gown material is not cytotoxic: cell viability at the standard extract concentration was 95.9–97.4% (requirement: at least 70%) [6]. Bacterial filtration efficiency of seven types of nonwoven products was 97.2–99.98%, and all 168 samples were impermeable to viruses. The gown showed both high air permeability ($875.6 \text{ dm}^3/(\text{m}^2 \cdot \text{s})$) and high bacterial filtration efficiency

(98.4%). This is explained by the fact that the main resistance to air flow is provided by the fine-fibre meltblown layer, and it shows that air permeability cannot substitute for barrier testing [7].

One gown out of 84 (1.19%) gave a positive sterility test result. The 95% Clopper–Pearson confidence interval for the contamination rate was 0.03–6.5%. Even 84 negative results would only show that the contamination rate does not exceed 3.5%, which is many orders of magnitude away from SAL = 10^{-6} . Sterility assurance therefore cannot be confirmed by testing finished products; it is ensured by validation and routine control of the sterilisation process [8], while the sterility test serves to detect gross failures. Routine monitoring of sterilisation cycles with biological indicators revealed a nonconformity in one cycle out of five, caused by a drop in relative humidity during preconditioning to 48% (requirement: 50–60%). FMEA likewise assigned the highest risk to sterilisation (RPN = 200) and packaging (RPN = 144).

During 36 months of real-time storage ($n = 48$), all indicators remained within the limits and sterility was maintained. Breaking force decreased by 3.6% and seal strength by 14.3%, so the factor limiting shelf life is the package seal rather than the gown fabric. Accelerated ageing results agreed with real-time results to within 0.04 N during the first three months and were slightly more severe thereafter, which shows that the shelf-life estimate is conservative. Results of the resistance test to external influences ($n = 60$) are shown in Fig. 1.

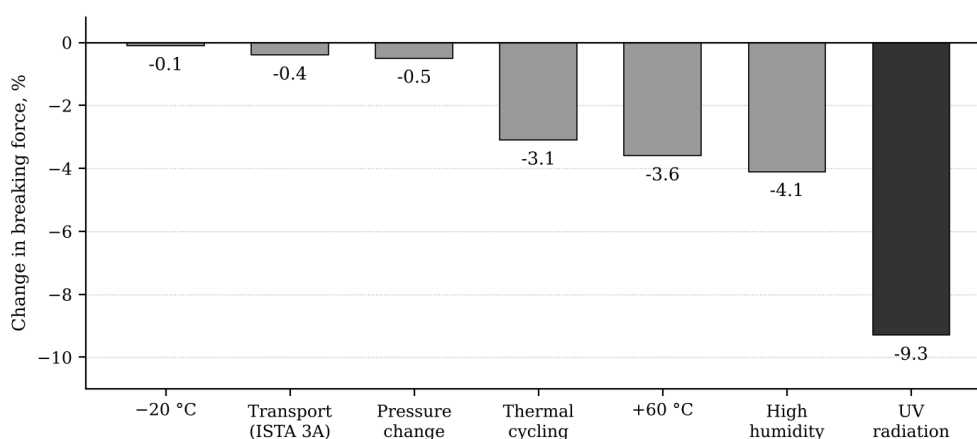


Fig. 1. Effect of external influences on the breaking force of the surgical gown

Sterility was maintained after all exposures, and breaking force stayed above the limit. The strongest effect came from ultraviolet radiation (–9.3%), associated with photo-oxidation of polypropylene; this supports the requirement to store gowns in opaque secondary packaging away from sunlight.

The two-stage assessment method was verified in three cases (Table 2). In the first stage, fulfilment of the mandatory requirements (sterility, biological safety, package integrity) is checked as $D = 0$ or $D = 1$; in the second stage, quality indicators are combined into the integral index I_q .

Table 2
Comparison of acceptance decisions under different assessment approaches

Case	Testing to GOST 12.4.280 and UzTR.148-008	Integral rating without mandatory requirements	Proposed two-stage method
Validation lots	Conforming	$I_q = 1.000$; accept	$D = 1$; $I_q = 1.000$; accept

Case	Testing to GOST 12.4.280 and UzTR.148- 008	Integral rating without mandatory requirements	Proposed two-stage method
Lot with positive sterility test	Conforming (sterility not tested)	Iq = 0.72; rework	D = 0; reject
Lot with 3 indicators below limits	Nonconforming (degree not determined)	Degree assessed	D = 1; Iq = 0.895; sorting

Current testing practice does not detect sterility nonconformity at all. Including sterility in the integral rating alongside other groups gives a non-sterile lot with excellent physical-mechanical indicators a score of 0.72 and merely sends it for rework. Under the proposed method such a lot is rejected at the first stage, which eliminates the risk of “compensation”. When group weights were varied by $\pm 20\%$, Iq stayed within 0.894–0.897 and the decision did not change. A deviation of a single indicator by up to 10% led to conditional acceptance, while a 20% deviation led to sorting or rework.

Conclusions

1. The sterile surgical gown made of SMS nonwoven fabric meets the requirements for all indicators that have established limits. The smallest quality margin belongs to mass per unit area and hygroscopicity ($K_z = 1.12$), and the lowest process capability to hygroscopicity and package seal strength ($C_{pk} = 1.00$). These indicators should be designated as priority control points in the production control plan.
2. Expression (1), which links the quality margin coefficient to the process capability index, makes it possible to set a target mean value for each indicator (at least 5.8% for hygroscopicity).
3. A sterility test cannot confirm $SAL = 10^{-6}$; therefore the results of sterilisation process validation and routine control, particularly humidity during preconditioning, should be treated as a mandatory part of the quality assessment.
4. The shelf life of the gown is limited by the package seal; of the external influences, ultraviolet radiation is the most damaging (-9.3%).
5. The two-stage assessment method reliably rejects non-sterile lots and grades nonconformities in quality indicators according to their importance; the decision is robust to $\pm 20\%$ changes in weighting coefficients.

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