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Research Article

A Two-Stage Approach to Quality Assessment of Sterile Medical Products Made of Nonwoven Fabric

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Shohobidinova Dilafruz Erkinjon qizi

Doctoral student, Namangan State Technical University, Namangan, Uzbekistan

Qosimov Axtam Akramovich

PhD in Technical Sciences, Associate Professor, Namangan State Technical University, Namangan, Uzbekistan

ABSTRACT

Conventional quality indices for medical textiles add up all measured properties into one score, which allows a safety failure to be hidden behind good mechanical results. This paper proposes a two-stage procedure for sterile nonwoven products. At the first stage four mandatory safety conditions are checked as a logical gate; at the second stage the remaining properties are reduced to relative values, combined inside each group by the «weakest link» rule and weighted across groups. Group weights were obtained from a three-round Delphi survey of 24 experts combined with pairwise comparison ($W = 0.79$; $CR = 0.053$). For a test batch with three sub-standard properties the method gives $I_q = 0.895$ and a «sorting or rework» decision, whereas a plain weighted mean gives 0.968 and conditional acceptance.

KEYWORDS

Nonwoven fabric, surgical gown, sterility, integral quality index, weakest link, Delphi method, analytic hierarchy process, acceptance decision.

INTRODUCTION

Disposable surgical gowns, drapes and masks made of spunbond–meltblown–spunbond (SMS) polypropylene form a protective barrier between the

surgical team and the patient. Their usefulness depends on properties of very different nature: sterility of the product, absence of cytotoxic residues,



resistance to penetration of microorganisms and liquids, tensile strength, integrity of the sterile barrier package and wearing comfort [8]. These properties are expressed in different units and are regulated by different documents – EN 13795-1 for barrier performance, EN 556-1 and ISO 11135 for sterility, ISO 10993 for biological safety and ISO 11607-1 for packaging [1–4].

In Uzbekistan such products are still tested against requirements written for protective clothing (GOST 12.4.280-2014) and for light-industry goods (technical regulation UzTR.148-008:2016). Barrier and sterility indicators are therefore not part of routine acceptance, and the laboratory report contains a list of separate «complies / does not comply» verdicts without a single conclusion on the batch. Classical qualimetry offers integral indices built as weighted sums of relative indicators [5, 6], but a weighted sum is compensatory by nature: a deficiency in one property can be offset by a surplus in another. For a sterile medical product this is unacceptable, because no level of tensile strength can compensate for a contaminated gown.

The aim of this work is to construct an assessment procedure that keeps the convenience of a single index but excludes compensation of safety-related failures.

METHODS

The object of the study was an SMS surgical gown (35 g/m², ethylene oxide sterilization) produced by two Uzbek enterprises. The indicators were divided into two sets. The first set includes conditions that must be met unconditionally: validated sterilization cycle with a negative sterility test (δ_1), cell viability not lower than 70 % according to ISO 10993-5 (δ_2), ethylene oxide residue within the ISO 10993-7 limit (δ_3) and a

tight package (δ_4). Each condition takes the value 1 or 0, and the result of the first stage is their product:

$$D = \prod_{i=1}^4 \delta_i \quad (1)$$

A batch with $D = 0$ is rejected without further calculation. For batches with $D = 1$ each measured property P_i is converted to a relative value with respect to its limit P_i^* ; for requirements of the type «not less than» $q_i = \min(1; P_i/P_i^*)$, for «not more than» $q_i = \min(1; P_i^*/P_i)$. Inside a group the lowest relative value is taken, and the groups are combined with weights m'_j :

$$Iq = \sum_{j=1}^k m'_j \cdot \min(q_{j1}, q_{j2}, \dots, q_{jn}), \quad \sum_j m'_j = 1 \quad (2)$$

Because every q is bounded by unity and the weights sum to one, Iq always lies in $[0; 1]$, and $Iq = 1$ means that every limit is met. To keep the information lost by truncation at unity, a quality margin coefficient $Kz = P_i/P_i^*$ (or its inverse) is reported for each property; it shows how far the result lies from the limit and is not bounded from above.

The procedure develops the qualimetric model proposed by the authors earlier [9]. The weights were obtained from a panel of 24 specialists selected from 67 candidates: eight represented manufacturers, six certification and regulatory bodies, five research institutes, three hospital operating units and two universities. All had at least ten years of experience (mean 17.4 years). The first Delphi round collected open opinions and fixed five indicator groups; the second used a 1–9 rating scale; the third used pairwise comparison matrices processed by the eigenvector method of the analytic hierarchy process [7].

RESULTS AND DISCUSSION

The spread of expert opinions decreased from round to round (coefficient of variation $0.31 \rightarrow 0.24 \rightarrow 0.18$).

Kendall's coefficient of concordance reached $W = 0.79$ ($\chi^2 = 75.8$; $p < 0.001$), and the consistency ratio of the aggregated matrix was $CR = 0.053$, well below the

accepted threshold of 0.10. The resulting weights for three risk classes are shown in Fig. 1.

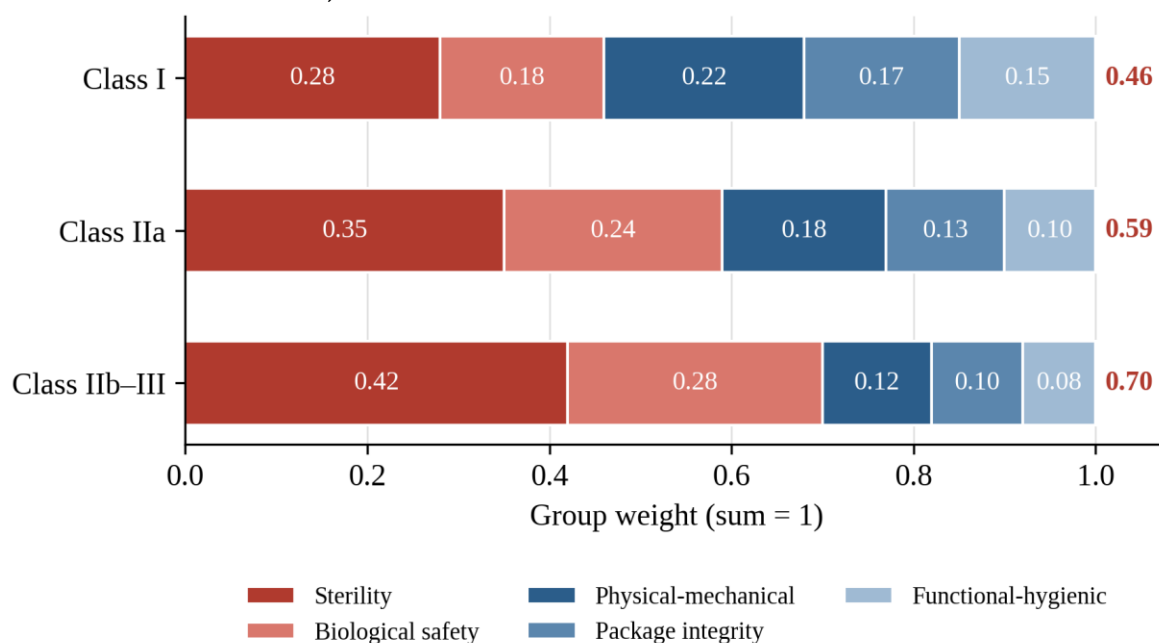


Figure 1. Group weights obtained from the Delphi-AHP survey for three risk classes (sum of the two left segments – share of safety-related groups)

Two observations follow from Fig. 1. First, sterility and biological safety together account for 46 % of the total weight even for low-risk Class I products, and their share grows to 59 % and 70 % for higher classes. Second, the ranking of the remaining groups does not change between classes. Both facts justify moving the safety groups out of the weighted sum into the first-stage gate: their influence is too large to be traded against comfort or strength, while the remaining three groups can be renormalized without distorting their

relative importance. For Class I the renormalized weights are 0.41 (physical-mechanical), 0.31 (package integrity) and 0.28 (functional-hygienic).

The decision rule attached to the index is given in Table 1. Its thresholds were chosen so that a 10 % shortfall in the lightest group still leads to conditional acceptance, while a twofold shortfall in strength leads to rejection.

**Table 1. Acceptance decisions for batches that passed the first stage (D = 1)**

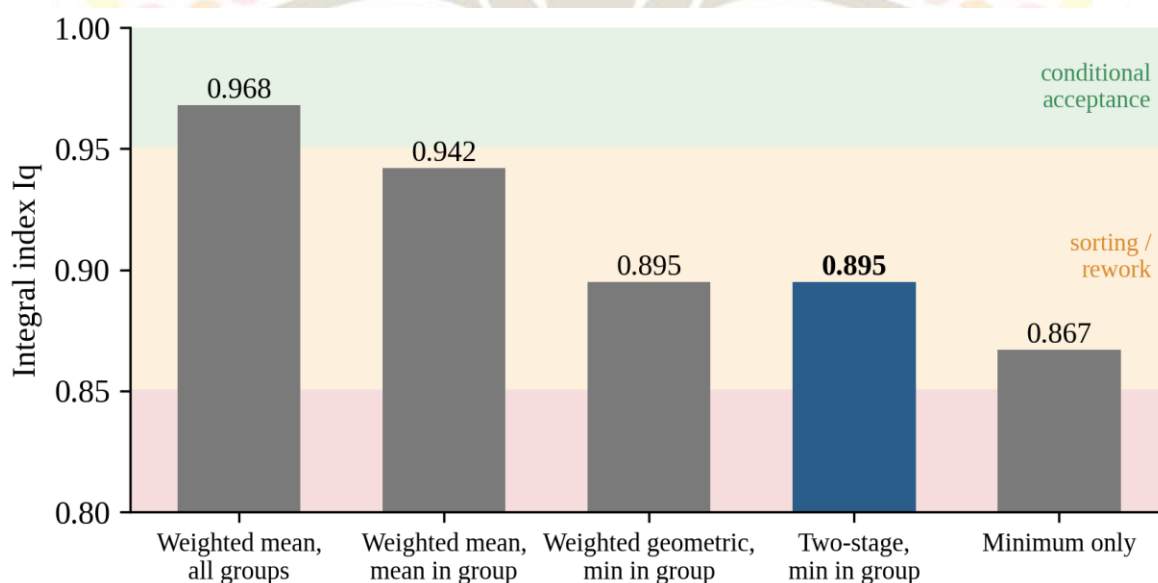
Iq	Batch state	Decision
1.000	All limits met	Accept
0.950–0.999	Minor nonconformity	Conditional acceptance, corrective action
0.850–0.949	Significant nonconformity	Sorting or rework, root-cause analysis
< 0.850	Critical nonconformity	Reject

To compare the proposed rule with common alternatives, a test batch was considered in which three properties were below their limits: tensile strength across the web 18.0 N (limit 20 N), seal strength of the package 1.3 N/15 mm (limit 1.5) and moisture absorption 4.6 % (limit 5 %). The relative

values are 0.900, 0.867 and 0.920, and the index by formula (2) is

$$Iq = 0.41 \cdot 0.900 + 0.31 \cdot 0.867 + 0.28 \cdot 0.920 \\ = 0.895$$

The same data processed by four other aggregation schemes are compared in Fig. 2.

**Figure 2. Integral index of the test batch under five aggregation schemes and the corresponding decision zones**

A weighted mean over all groups, including sterility and biological safety, places the batch in the zone of conditional acceptance (0.968): the perfect safety groups «dilute» the three deficiencies. Averaging inside groups instead of taking the minimum also inflates the score (0.942). Only schemes that use the minimum inside a group keep the batch in the sorting zone, and among them the proposed two-stage scheme has the advantage of a transparent additive form that can be explained to a laboratory technician. A sensitivity check in which each weight was varied by $\pm 20\%$ with renormalization of the others changed the index only within 0.894–0.897, so the decision is robust to reasonable disagreement among experts.

The most instructive case, however, is a batch with a positive sterility test and excellent physical properties. In the existing practice such a batch passes, since sterility is not tested. In a compensatory index it would receive $1 - 0.28 = 0.72$ points and be sent for rework. In the proposed procedure it is rejected at the first stage, which corresponds to the logic of EN 556-1: sterility is a condition, not a degree of quality.

CONCLUSIONS

1. Separating mandatory safety conditions from graded quality properties removes the main weakness of additive quality indices for sterile medical textiles – the possibility of compensating a safety failure.
2. The «weakest link» rule inside groups prevents a single poor property from being hidden by good neighbours, while the additive form across groups keeps the index interpretable; the index is bounded in $[0; 1]$ and is complemented by quality margin coefficients.

3. Expert weights obtained by the Delphi–AHP procedure are statistically consistent ($W = 0.79$; $CR = 0.053$) and show that safety-related groups dominate (0.46–0.70 of the total weight), which supports their removal into the gate.

4. On a test batch the procedure produced a stricter and better justified decision than four alternative schemes and proved insensitive to $\pm 20\%$ variation of the weights.

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