STERILE PAPER-PLASTIC BARRIER SYSTEM FOR PRESSURE STERILIZATION

by

Yao SHEN[a], Baohua LI[b*], Zhuoya YAO[c*], Yingjie HOU[a], Xiangang LI[d], Shanchao ZUO [d], Xi LU[a], and Suinan LI[a]

[a] Jiaozuo People's Hospital,
Xinxiang Medical University Affiliated Jiaozuo
People's Hospital, Jiaozuo, China
[b] Beijing Chao-Yao Hospital Capital Medical University, Beijing, China
[c] People's Hospital of Henan Province, Zhengzhou, China
[d] Shinva Medical Instrument Co., Ltd., Zibo, China

Original scientific paper
https://doi.org/10.2298/TSCI2403211S

The sterile paper-plastic barrier system for packaging sterilized medical equipment is studied, the main factors affecting its breakdown are revealed, and the inhalation rate during the pressure sterilization is experimentally analyzed. The results offer a new window of opportunity for a stricter risk-analysis and a robust strategy for the pressure sterilization, and this paper can be served as an example of strict clinical applications.

Key words: *sterile barrier system, gas expansion coefficient, pressure sterilization*

Introduction

The sterile paper-plastic barrier system [1-3] is used for packaging final sterilized medical equipment to protect sterilized items. It complies with the requirements and test methods of the pharmaceutical industry standard of the People's Republic of China, the EN865-5 standard for packaging materials and systems for sterilizable medical equipment in part 5: heat-sealed, self-sealing, and rolled pouches in combination with paper and plastic film.

Prefabricated sterile products are sealed at ambient temperature to maintain closure. In the preparation phase, the sterilizer chamber is forced by a vacuum system to form a negative pressure, then the sterilizing medium is fed into the sterilizer chamber through a steam line, the rate of pressure change in this process is in accordance with the requirements of the EN285 standard. The sterilization medium in the autoclave is saturated vapor [4, 5]. The pressure exerted by saturated steam influences the expansion of the gas in the paper-plastic sterile barrier system and may cause the sterile barrier system to be collapsed. There is a correlation between the rate of pressure variation in the chamber of the pressure sterilization equipment and the coefficient of gas expansion of the sterile paper-plastic barrier system.

There are many different types of the pharmaceutical packaging materials, among which the paper-plastic packaging material is the most used one with good performance [6], it is environment-friendly and can be also used for food packaging [7].

* Corresponding authors, e-mail: 13521202831@163.com; yao2709@126.com

The paper-plastic sterile barrier system is made of medical dialysis paper, which is a heat-proof laminated CPP/PET film. It is an optional packaging material for a variety of sterilization methods. It can be used for precision packaging of implants, base, lumen and dressings in hospital. In the process of sterilization or transport, the gas in the packaging is thermally expanded or extruded by external forces, which will produce a large impact on the bag body and the heat-sealing edge. If the packaging material is poorly tolerant to internal pressure, it will be deformed under the impact of the gas and even result in bags breaking. The tolerance of the internal pressure of the pharmaceutical bag is an important factor affecting its susceptibility to bags breaking in sterilization, transport and other aspects, which is related to the heat sealing of the sealing edge, the flexibility of the packaging material and other factors.

Paper-plastic sterile barrier system

According to ISO/TS 16775 and WS310.2-2016 standards, the sterile package of instruments is required from the bag closure, paper-plastic packaging bag space reserved, loading height, sterilization loading method, to the performance of the medical heat-sealing machine for testing, and each requirement has to be verified by the relative validations, which also clarifies the weight demand and the specified standards. The paper-plastic sterile barrier systems used in hospitals are factory tested according to GB/T 19633 and YY/T 0681 standards and the quality can satisfy the needs for preparing sterile barriers. Although part of the parameters of the preparation process are recommended by the manufacturer, the clinical use of instrument packs to meet the needs of a single procedure always results in large and heavy instrument packs. Paper-plastic wrapping bags are available in sizes that allow the wrapping of larger and heavier plastic surgery instruments.

Surface tension of the paper-plastic packaging barrier system

The manufacturer makes the bag-making machine runs at 130~200 °C and 60~100 rpm. The dialysis paper and composite film are transformed into a composite bag along the glue-coated part using the microwave heat seal method to form a sterile medical packaging bag. The explosion test is carried out in the standard atmosphere, and the closed packaging is placed in the test device and carefully inserted into the device, the test is started by initiating the aeration process, and pressing it until the paper-plastic bag explodes in order to determine the design value of the barrier system.

The top of the paper-plastic sterile barrier system resembles an arch once it has been inflated, its surface tension can be approximately calculated by the Young-Laplace equation [8]:

$$\sigma = \frac{1}{4} D(p_{\text{in}} - p_{\text{out}}) \tag{1}$$

where σ is the surface tension, D – the inflated diameter, p_{in} – the air pressure inside the bag, and p_{out} – the atmospheric pressure. eq. (1) is valid for a spherical shape, it is widely used in the bubble electrospinning [9-14].

When the surface tension is larger than the tensile strength of the bag, breakdown occurs. According to eq. (1), a larger curvature radius leads to a larger surface tension, so the flat surface is easy to be broken under the inflation pressure or an external force.

According to the gas state equation:

$$p_{\text{in}} V = \text{R}T \tag{2}$$

where R is the molar gas constant, T – temperature inside the bag, and V – the inflated air volume of the bag, eq. (1) becomes:

$$\sigma = \frac{1}{4} D\left(\frac{\mathrm{R}T}{V} - p_{\mathrm{out}} \right) \tag{3}$$

Equation (3) implies a small volume is peculiarly prone to breakdown.

Pressure change during the inflation and the exhaust is illustrated in fig. 1, during the inflating process, the pressure increases with time, while an opposite process occurs during the exhausting process. When the inflating process stops, the pressure keeps unchanged until exhaust. During the exhausting process, the surface tension is released partially, and some part of surface become more plat, so it is more prone to breakdown as shown in fig. 1(b).

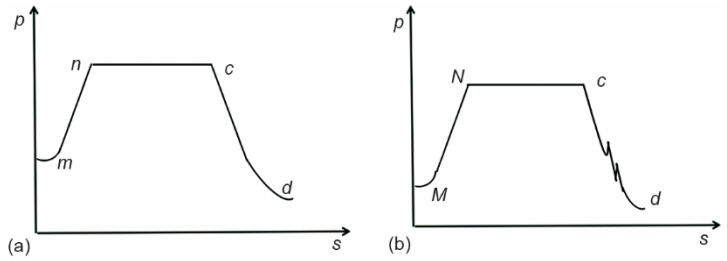

Figure 1. Pressure change during the inflation and the exhaust;
(a) normal inflating and exhausting process and
(b) breakdown during the exhausting process

Pulse steam sterilizer procedure

The pulse steam sterilizer procedure, see fig. 2, is divided into five stages: the pulse, heating, sterilization, evaporation, and drying. During the pulsating phase of the pre-sterilization process, the ability to remove cold air from the sterilization chamber determines the overall sterilization efficiency. In the preparation phase of sterile, the inner chamber of the sterilizer is forced by a vacuum system to create a negative pressure, and the sterilizing medium (saturated water vapor) is fed into the inner chamber of the sterilizer via a steam pipe, the rate of change of pressure in this process complies with the requirements of the EN 285 standard. During pulsating evacuation, the pressure inside the sterilizer chamber is lower than the pressure inside the paper-plastic bag, which is expanding. If the vacuum pump pumping rate is higher, it will cause the paper-plastic bag to expand sharply. During the pulsing vapor inlet, the pressure inside the sterilizer chamber exceeds the pressure inside the paper-plastic bag, which is being compressed. If the steam inlet rate is high, the bag will be compressed sharply. There may be short-term pressure shift in the process of negative to positive pressure. After the pulsation phase of repeated vacuuming and steam injection, the sealing pressure of the paper-plastic bags is gradually reduced, which may cause the bags to burst. After sterilization, the cavity enters the steam discharge stage with a significant pressure change. After the steam has been exhausted to a certain pressure, the vacuum system is activated and the inner cavity is forced to exhaust steam. The pressure quickly falls into a negative state and the sterilization process enters the drying stage. In the pulsation phase, the pressure at its closure is reduced by repeatedly exhausting the expansion and inflation of the compressed paper-plastic

bag, which makes the expansion of the paper-plastic bag at the closure of a greater chance of bursting the bag. From fig. 2, a similar thermal oscillation is observed as that in [15].

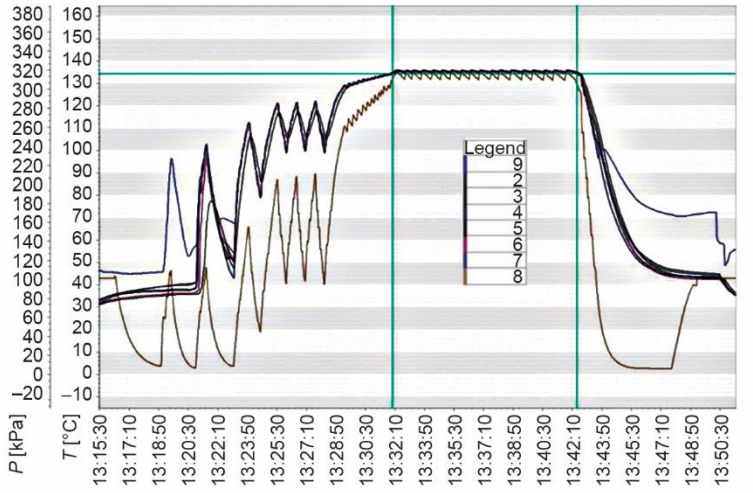

Figure 2. The pulse steam sterilizer procedure

Discussion and conclusion

During the pressurized steam sterilization process, a number of packages of lightly heavy surgical instruments in paper-plastic packages were repeatedly subjected to a bag break after sterilization. Through interrogation experiments, it was found that the ambient temperature validated paper-plastic packaging IS011607-2-2006 *Final Sterilised Medical Device Packaging Part 2: Confirmation Requirements for Forming, Sealing and Assembly Processes* were all satisfied, but the burst test validation method for paper-plastic packaging for high temperature and high pressure environments was not incorporated. Considering that the testing of paper-plastic packaging is at standard atmospheric pressure at ambient temperature, the addition of burst testing of the equipment air inlet rate and the gas expansion coefficient of the paper-plastic aseptic barrier system will better enable the function of the aseptic barrier in special environments.

Conflict of interest

This work does not have any conflicts of interest.

References

[1] de Roeck, A., *et al.*, Effect of High Pressure/High Temperature Processing on Cell Wall Pectic Substances in Relation to Firmness of Carrot Tissue, *Food Chemistry*, *107* (2008), 3, pp. 1225-1235
[2] Dunkelberg, H., Schmelz, U., Determination of the Efficacy of Sterile Barrier Systems Against Microbial Challenges During Transport and Storage, *Infection Control and Hospital Epidemiology*, *30* (2009), 2, pp. 179-183
[3] Tourvieilhe, L., *et al.*, Reevaluating the Shelf Life of Sterilized Packaged Items via a Risk-Analysis Study, *Annales Pharmaceutiques Francaises*, *78* (2020), 3, pp. 264-272
[4] Rowe, T. W. G., Kusay, R., Steam Sterilization, *Lancet*, *2* (1961), Sept., pp. 604-605

[5] Hoyos, J. P. C. M. V. G., *et al.*, Steam Sterilization Does Not Require Saturated Steam, *Journal of Hospital Infection, 97* (2017), 4, pp. 331-332
[6] Chen, H. Q., *et al.*, Preparation and Properties of Paper-Plastic Laminating Adhesive Used for Medical Packaging Materials, *Polymers for Advanced Technologies*, *26* (2015), 9, pp. 1065-1069
[7] Yang, C. L., *et al.*, GC-MS Studies on the Contaminants in Paper-plastic Food Packaging Materials, *Green Printing and Packaging Materials*, *380* (2012), Jan., pp. 282-285
[8] Chen, R. X., On Surface Tension of a Bubble Under Presence of Electrostatic Force, *Thermal Science, 19* (2015), 1, pp. 353-355
[9] He, J.-H., *et al.* The Maximal Wrinkle Angle During the Bubble Collapse and Its Application to the Bubble Electrospinning, *Frontiers in Materials*, *8* (2022), 800567
[10] Qian, M. Y., He, J. H., Collection of Polymer Bubble as a Nanoscale Membrane, *Surfaces and Interface, 28* (2022), 101665
[11] He, C. H., *et al.*, Taylor Series Solution for Fractal Bratu-Type Equation Arising in Electrospinning Process, *Fractals, 28* (2020), 1, 2050011
[12] Li, X. X., He, J.-H., Bubble Electrospinning with an Auxiliary Electrode and an Auxiliary Air Flow, *Recent Patents on Nanotechnology, 14* (2020), 1, pp. 42-45
[13] Zuo, Y. T., Liu, H. J., Effect of Temperature on the Bubble Electrospinning Process and Its Hints for 3-D Printing Technology, *Thermal Science, 26* (2022), 3B, pp. 2499-2503
[14] Li, X. X., *et al.*, Multiple Needle Electrospinning for Fabricating Composite Nanofibers with Hierarchical Structure (in Chinese), *Journal of Donghua University* (*English Edition*), *38* (2021), 1, pp. 63-67
[15] Liu, F. J., *et al.*, Thermal Oscillation Arising in a Heat Shock of a Porous Hierarchy and Its Application, *Facta Univ.-Ser. Mech., 20* (2022), 3, pp. 633-645

Paper submitted: December 15, 2022
Paper revised: March 15, 2023
Paper accepted: May 24, 2023