A DRY STERILIZATION PROCESS FOR STERILIZED PRODUCTS AFTER PRESSURE STEAM STERILIZATION

by

Zhuoya YAO[a], Qing ZHANG[b*], Yao SHEN[c*], Xiangang LI[d], Xiaozhi WANG[c], Meng ZHAN[a], Junfeng WANG[a], Junhui GENG[a], and Chunmei SHAO[e]

[a] Henan Provincial People's Hospital, Zhengzhou University People's Hospital, Zhengzhou, Henan, China
[b] Peking Union Medical College Hospital, Beijing, China
[c] Jiaozuo People's Hospital, Jiaozuo, China
[d] Shinva Medical Instrument CO., Ltd., Zibo, China
[e] The First People's Hospital Shangqiu, Shangqiu, China

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A dry sterilization process is designed as a post-processual technology of the pressure-steam sterilization. Three experiments are carried out to study the effects of negative pressure, pulsating air, and pulsating steam, respectively, on the process. Antoine's formula is used to predict the relationship between the vapor pressure and the temperature, which can be applied in practice.

Key words: *pressure steam sterilization, drying of sterilized products, post-processual, technology, energy-conservation*

Introduction

The medium of steam sterilization is the water vapor with a certain range of steam drying degree from 97% to 100%, generally the sterilized steam is considered as a saturated steam. Many factors can affect the heat conduction of the sterilization process [1]. The saturated steam has to release a large amount of latent heat during the humid heat sterilization process to kill microbial proteins and to achieve the purpose of sterilization [2-5]. However, it is unable to preserve damp products during usage and it can easily breed microorganisms again. A post-sterilization process is needed to remove moisture from damp products which have reached sterilization conditions. The standardized dry process is widely used in hospitals. In this paper, we compare three post-sterilization dry processes, the advantages and disadvantages of each drying mechanism are interpreted, and the experimental results can be directly used for various sterilization and dry processes.

Negative pressure vacuum drying of post-sterilization process

The evaporation of water violently depends on the negative pressure in vacuum status within 0.05-0.1 bar. The boiling point of water is lower at vacuum status for –90 kPa and the water in sterilization package is evaporated. In this way the heat radiation in the sterilizer jacket is used to dry the sterilizer package. With respect to the instrument package, the specif-

* Corresponding authors e-mail: zhangqing9191@163.com; shenyao332600@126.com

ic heat capacity of the metal equipment in the package is lower than that of the dressing cotton. During the post-sterilization process, dressings absorb the same amount of heat radiation as metalic instruments, resulting in a lower temperature increase, therefore, the temperature of the dressing package is lower after drying. This drying mechanism is to evaporate the moisture when the boiling point of water is lower. As this sterilization and dry process depends on heat radiation from the sterilizer jacket, its efficiency of heat transfer is lower. Figure 1 shows the vapor pressure change of the sterilization and dry process.

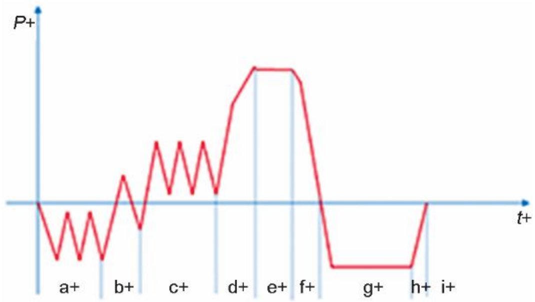

Figure 1. Negative pressure vacuum drying;
Period: a - pulsation, b - crossing pressure pulsation, c - positive pressure pulsation, d - temperature rise, e - sterilization, f - aerofluxus, g - vacuum drying, h - equilibrium, and i - termination

Pulsating air drying of post-sterilization process

The pulsating air drying is to cut down the pressure in the cavity of the sterilizer below –88 kPa with the use of a mechanical pump, a filtered air is imported during this process. By means of the heat-transfer medium, air, the heat of the jacket is transferred to the sterilizer package, and the pressure rises to –20 kPa gradually in this process. The water in the package is volatilized as usual. By repeating operation of the mechanical pump to supply the pressure in the sterilizer cavity less than –88 kPa for three times, a lot of water is disappeared from the package. The process of sterilization and drying utilizes the alternation of vacuum and atmospheric pressure pulsation in the drying chamber. The drying efficiency depends upon the microstructure of the material, moisture migration and diffusion within the material. The principle of drying is the consequence of the combined action of the heat transfer of cold air and the low temperature boiling and evaporation with the lower boiling point of water under negative pressure. Figure 2 shows the vapor pressure change of the pulsating air drying process.

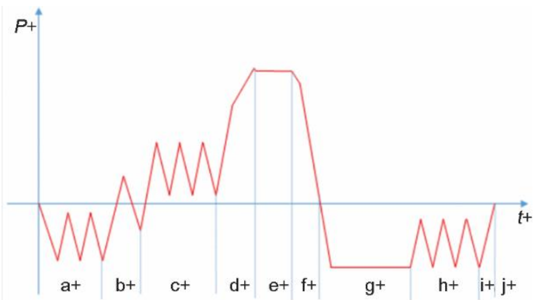

Figure 2. Pulsating air drying;
Period: a - pulsation, b - crossing pressure pulsation, c - positive pressure pulsation, d - temperature rise, e - sterilization, f - aerofluxus, g - vacuum drying, h - pulsating air drying, i - equilibrium, and j – termination

Pulsating steam drying of post-sterilization process

The post-sterilization technology of pulsating steam drying is to drop the gas in the sterilizer from a high pressure to the atmospheric pressure after sterilization. As part of the heat is released, the temperature of the sterilizer package becomes lower. Utilizing the mechanical pump to cut down the pressure in the sterilizer cavity below –88 kPa, and then inputting steam into the cavity until the pressure reaches –78 kPa. The process is repeated over and again. The steam temperature will be increased under the negative pressure, the sterilizer package is, therefore, heated and its temperature is increased, as a result, a lot of water is disappeared from the package because of the boiling point of water under the negative pressure becomes lower and the heat makes the evaporation faster. The principle of drying is the consequence of the combined action of the heat transfer of the jacket, heating of the negative pressure steam and the low temperature boiling and evaporation with the lower boiling point of water. Figure 3 shows the vapor pressure change of the pulsating steam drying process.

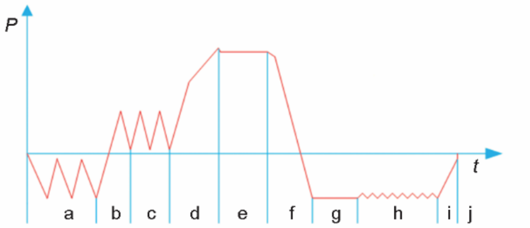

Figure 3. Pulsating steam drying;
Period: a - pulsation, b - crossing pressure pulsation, c - positive pressure pulsation, d - temperature rise, e - sterilization, f - aerofluxus, g - vacuum drying, h - pulsating steam drying, i - equilibrium, and j - termination

Calculation of vapor pressure and temperature

The vapor pressure of water is due to thermodynamic equilibrium of the water vapor and its condensed state. Under certain temperature, the vapor will be condensed into water under pressure, on the other hand, the water will evaporate into a steam when the acted pressure is decreased, this is the reason why we employ the negative pressure during drying process during sterilization, the water adhered to the packaging material will be volatilized completely and thus the wet package can be avoided.

The vapor pressure can be predicted by the temperature using the Antoine eqs. (1) and (2), which reads:

$$\ln P = a - \frac{c}{T - b} \tag{1}$$

where P [MPa] is the saturated vapor pressure, T [K] – the temperature, a, b, and c are constants, which can be determined experimentally. After experimental identification of the parameters in eq. (1), we obtain:

$$\ln P = 9.3876 - \frac{3826.36}{T - 45.47}, \qquad 290 < T < 500 \tag{2}$$

where $T = t + 273.15$, where t is temperature in °C.

Discussion and conclusion

In order to improve the accuracy, eq. (1) can be replaced by the Frost-Kalkwarf equation to estimate the vapor pressure:

$$\ln P = A + \frac{B}{T} + C \ln T + \frac{D}{T^2} P \tag{3}$$

where A, B, C, and D are constants, and can be determined experimentally. As this equation does not give explicitly the relationship between the pressure and temperature, and it is not widely used in practical applications.

The ST79 standard issued by the Association for the Advancement of Medical Instrumentation (AAMI) indicates that it is unreasonable to guarantee the quality of sterilization only by prolonging the sterilization cycle or increasing the sterilization temperature, it also points out that the quality procedure of pressure steam sterilization should base on the records of objective performance data, see 2017 Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities, ANSI/AAMI ST-2017.

Risk assessment of all aspects of steam sterilization should be performed to identify possible risks associated with employees and patients, in this way, we can define and quantify the existing risks, the establishment of the standard needs to be evaluated according to the wet package of the sterilizer. The research described in this manuscript is to demonstrate the whole sterilization process with three drying methods, revealing different drying mechanisms, *i. e.*, the negative pressure drying, the pulsating air drying and the pulsating steam drying. Our experiment shows that a high energy consumption is observed in the negative pressure drying, a low conduction efficiency in the pulsating air drying, and a high requirements of steam quality in the pulsating steam drying.

The negative pressure drying and the pulsating air drying are widely used in practice, while the pulsating steam drying has the advantage in improving the drying efficiency and energy saving. The Antoine equation given in eq. (2) provides a reference for selecting an appropriate post-sterilization process to improve drying quality of medical devices, and to ensure the quality of sterilized products, furthermore, it can be used to optimize the product design of sterilized products, improve the level of safe usage of special equipment and improve the drying degree and sterilization effect of sterilized products and decrease the consumed energy.

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