EFFECT OF NON-CONDENSABLE GAS ON HEAT CONDUCTION IN STEAM STERILIZATION PROCESS

by

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Non-condensable gas has an adverse effect on heat conduction in pressure steam sterilization. An experiment was carefully designed to study the effect, and a semi-empirical formulation is obtained to predict the maximal temperature difference between outside and inside of a package. This paper gives a systematical insight into the non-condensable gas effect, and there is a threshold of the non-condensable gas concentration, beyond which the thermal sterilization becomes invalid for complete killing microorganisms.

Key words: *pressure steam sterilization, non-condensable gas, saturated steam, thermal conductivity*

Introduction

Thermal sterilization is one of the most reliable, widely used and earliest used sterilization methods in the world, the decontamination method has been proved to be extremely simple yet very remarkably effective [1-12]. Saturated steam at high temperatures (generally from 121 °C to 134 °C) has been used in sterilization process, sterilized products are put into an autoclave and then are heated through pressurized steam to kill all microorganisms including spores. The device's exposure time to steam changes from 3 to 15 minutes, depending on the concentration of the non-condensable gas and the generated heat. Three major factors of sterilization process are the exposure time, the temperature and the concentration of saturated steam.

It is of great importance to kill all microorganisms during the sterilization process, among three major factors affecting the sterilization process, the temperature is of extreme importance. It would be ideal that the temperature on the outside and inside of the package reach their maximum at the shortest time with minimal difference. In surgery, all medical devices should be sterilized, and in the sterilization process, the amount of non-condensable gases (carbon dioxide, nitrogen, and oxygen) should be very low. It was reported that even a rather small fraction of non-condensable gas (below 1%) will seriously hamper sterilization process [1]. The non-condensable gases involved in the steam will great affect the temperature distribution on the package, and it is necessary to have a fast prediction to the temperature difference between the outside and inside of the package in an order to guarantee an absolute safety of the sterilization process. In this paper we will study the effect of the non-condensable gas involved in the water vapor on sterilization process.

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Experiment

High pressure steam has a bactericidal effect, mainly because of a certain steam under pressure can rapidly penetrate to the inside of a device, at the same time, steam can release the latent heat when it is condensed into water, and the body temperature rises rapidly, so as to achieve the purpose of sterilization. A series of experiment were designed to study experimentally the effect of the concentration of the non-condensable gas in the sterilizer on the thermal conduction during the pressure steam sterilization process.

The MAST-A-1200 pulsating vacuum sterilizer is used in our experiment, the rate of device leakage is 0.10 kPa/min, and the chamber's pressure increases at a rate of 100 kPa/min. During the experiment no pulsation stage and replacement stage occur, and the sterilization temperature is 134 °C, chamber pressure limit is 211 kPa. The experimental set-up is illustrated in fig. 1.

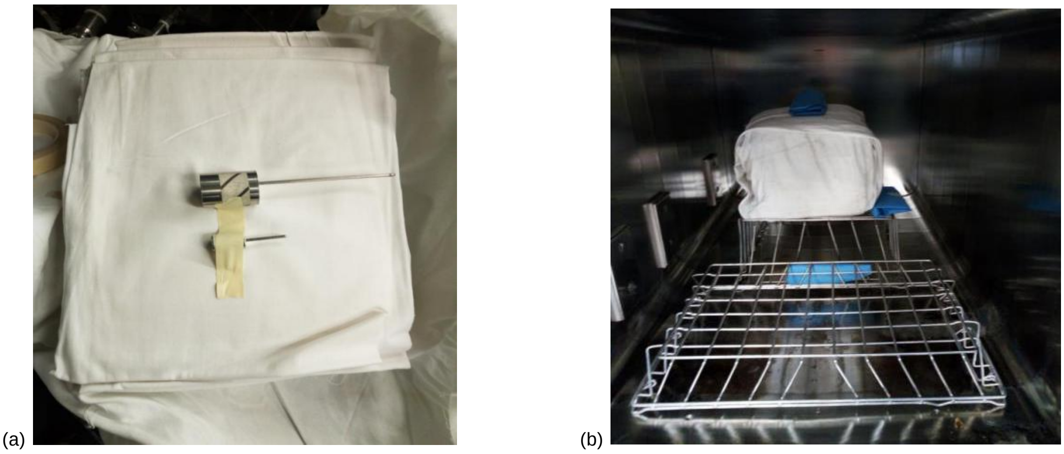

Figure 1. Experimental set-up; (a) two probes are placed in the standard package, (b) standard packages and other probes placed in sterilizers; the blue one is the probe wrapped in non-woven fabric (*for color image see journal web site*)

Eight experiments were carried out with different concentrations of non-condensable gas, the maximal and minimal temperatures outside and inside of the package were recorded from each experiment, which were listed in tab. 1. The general temperature changes during the thermal sterilization is illustrated in fig. 2.

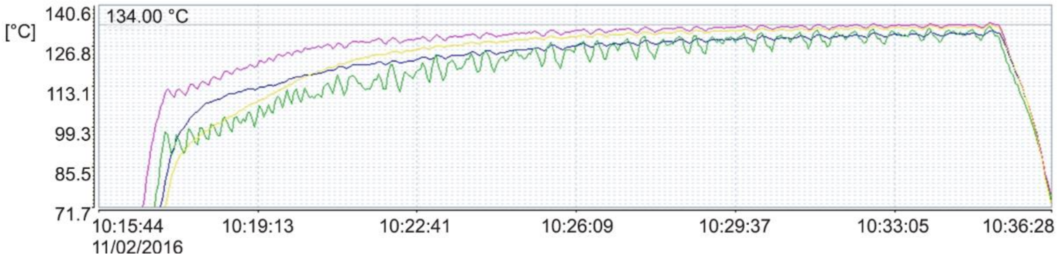

Figure 2. Temperature changes change during the thermal sterilization in and outside package (*for color image see journal web site*)

Table 1. Maximal and minimal temperatures outside and inside of the package at different concentration of non-condensable gas.

Exp.	Maximal temperature in package	Minimal temperature in package	Maximal temperature outside package	Minimal temperature outside package	Exposure time	Concentration of non-condensable gas
1					18 min 40 s	100
2	133.19 °C	131.71 °C	135.33 °C	133.94 °C	5 min 49 s	–
3	135.22 °C	134.14 °C	135.45 °C	134.48 °C	3 min 39 s	0.1542
4	134.74 °C	132.91 °C	135.41 °C	134.13 °C	3 min 46 s	0.2664
5	132.28 °C	128.49 °C	135.37 °C	134.01 °C	3 min 56 s	1.5309
6	127.78 °C	119.34 °C	135.08 °C	133.47 °C	4 min 36 s	2.2044
7					5 min 43 s	11.1556
8					11 min 15 s	13.3867

Theoretical analysis

When the high pressure steam meets a solid surface, the steam's kinetic energy is converted into the pressure energy. According to the Bernoulli equation [13]:

$$\frac{1}{2}u^2 + \frac{P}{\rho} = B \tag{1}$$

where u is the steam velocity, P – the steam pressure, ρ – the steam density, and B – the Bernoulli constant, when the steam meets on a solid surface, the steam's velocity is almost zero, and the surface pressure increases. This increased steam pressure is helpful for the steam to penetrate into the inside of a package.

The heat conduction can be written in the form

$$\frac{\mathrm{d}}{\mathrm{d}x}\left(k\frac{\mathrm{d}T}{\mathrm{d}x}\right) = Q \tag{2}$$

with initial conditions:

$$T(0) = T_0 \tag{3}$$

$$k\frac{\mathrm{d}T}{\mathrm{d}x}(0) = K\frac{\mathrm{d}T}{\mathrm{d}x}(0) \tag{4}$$

where T is temperature, k and K – thermal conduction coefficients of package and steam, respectively, T_0 – the sterilization temperature, in our experiment T_0 = 134 °C.

The steam involves vapor and non-condensable gas, so the thermal conduction coefficient can be calculated through the following formulation:

$$K = c_1k_1 + c_2k_2 \tag{5}$$

where k_1 and k_2 are thermal conduction coefficients of vapor and non-condensable gas, respectively, c_1 and c_2 – the concentrations of vapor and non-condensable gas, respectively, it follows that:

$$c_1 + c_2 = 1 \tag{6}$$

The initial condition of eq. (4) can be written in the form:

$$k\frac{\mathrm{d}T}{\mathrm{d}x}(0) = K\frac{\mathrm{d}T}{\mathrm{d}x}(0) = (c_1k_1 + c_2k_2)q = [(1-c_2)k_1 + c_2k_2]q \tag{7}$$

where q is steam's heat flux density.

Solving eq. (2) with initial conditions of eqs. (3) and (7), we have:

$$T = \frac{\frac{1}{2}Qx^2 + [(1-c_2)k_1 + c_2k_2]qx + T_0k}{k} \tag{8}$$

The temperature difference between outside and inside of the package is:

$$\Delta T = \frac{h\{Qx + [(1-c_2)k_1 + c_2k_2]q\}}{k} \tag{9}$$

where h is the thickness of the package.

The maximal temperature difference reads:

$$\Delta T_{\max} = \frac{h\{Qh + [(1-c_2)k_1 + c_2k_2]q\}}{k} = \frac{h\{Qh + [k_1 + (k_2 - k_1)c_2]q\}}{k} \tag{10}$$

Equation (10) reveals that a higher concentration of non-condensable gas results in a higher temperature difference:

$$\Delta T_{\max} \propto c_2 \tag{11}$$

According to our record given in tab. 1, we can calculate the temperature difference between outside and inside of the package, which are listed in tab. 2 and illustrated in fig. 3.

Table 2. Temperature difference between outside and inside of the package

Average temperature outside	Average temperature inside	Temperature difference	Concentration of non-condensable gas
134.68	134.96	0.28	0.1542
133,82	134.77	0.95	0.2664
130.38	134.69	4.31	1.5309
123.56	134.27	10.71	2.2044

Using the least square method, we have:

$$\Delta T_{\max} = 4.5707c_2 - 0.6863 \tag{12}$$

Equation (12) reveals that the concentration of non-condensable gas greatly affects the temperature distribution on the package, as a result, the bactericidal effect will be remarkably affected.

Discussion and conclusions

Temperature difference between outside and inside surfaces should be as small as possible to have a maximal bactericidal effect. The high pressure steam sterilization requires accurate prediction of temperature distribution. The sterilization efficiency, F_0, can be calculated using the following formula [14, 15]:

$$F_0 = \Delta t 10^{(T-121)/10} \tag{13}$$

where Δt is the exposure time and T – the surface temperature.

From eq. (13), we have:

$$\frac{\Delta F_0}{F_0} = \frac{\Delta T}{10} \ln 10 \Delta t \tag{14}$$

In case ΔT = 1 °C, this will lead to about 23% prediction error of the killing rate when the exposure time is 1 minute.

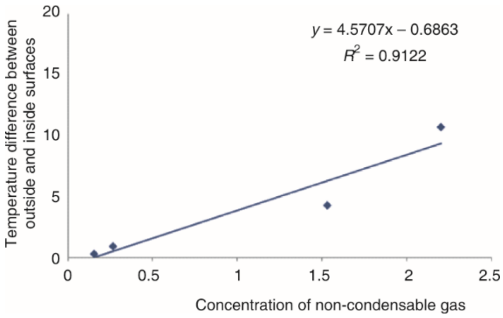

Figure 3. Effect of concentration of non-condensable gas on temperature distribution

According to FDA-GMP, EN285 and other related specifications, the temperature consistency required in the chamber shall be less than 1 °C, in most cases the temperature difference should be less than 0.5 °C.

In surgery, the killing rate should be larger than 95%, this requires:

$$\frac{\Delta F_0}{F_0} = 5\% \tag{15}$$

From eq. (14), we have:

$$\Delta T = \frac{10 \Delta F_0}{\Delta t F_0 \ln 10} = \frac{10}{\Delta t \ln 10} \times 5\% = \frac{0.217}{\Delta t} \tag{16}$$

In view of eq. (12), we have:

$$\Delta T_{\max} = 4.5707 c_2 - 0.6863 = \frac{0.217}{\Delta t} \tag{17}$$

Equation (17) gives a relationship among the temperature difference, concentration of non-condensable gas, and exposure time. The results are listed in tab. 3.

Table 3. Threshold values for non-condensable gas with different exposure time

Exposure time [minutes]	1	2	3	4	Infinite
Concentration of non-condensable gas	0.197	0.174	0.166	0.162	0.150

In the previous theoretical analysis, we use a continuum model. Ezzat *et al.* [16], suggested that a fractional Fourier law of heat conduction should be adopted, they used fractional time in their model, however, it might be better to use fractional space or fractal derivative [17-21] to give an exact description of the heat conduction in the sterilization process. Additionally, nanofiber membranes [22-24] with extremely high penetration are very much promising in sterilization process.

We conclude that the higher the non-condensable gas content is, the more detrimental to the heat conduction in the sterilization process. According to above analysis, we conclude that concentration of the non-condensable gas in practical applications should be less than 0.15%.

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