STUDY ON TEMPERATURE DELAY OF NON-METALLIC MEDICAL INSTRUMENTS IN PRESSURE STEAM STERILIZATION

by

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This study explored the influence of non-metallic medical instruments in the pressure steam sterilization process. An experiment was designed by using an electronic dynamic monitoring device to record the temperature, time and pressure of non-metallic medical instruments of different materials in the process of pressure steam sterilization. The results show that the medical instruments with wood or silica gel materials, especially those with lumen structure, are prone to temperature delay, resulting in insufficient sterilization time and greater safety risks.

Key word: *pressure steam sterilization, material, medical instruments, condensate water*

Introduction

The pressure steam sterilization is the most commonly used sterilization method in Central Sterile Supply Department (CSSD), and its sterilization quality is closely related to the occurrence of nosocomial infection. Its working principle is to use a saturated steam as the moist heat sterilization medium. During the sterilization process, when the saturated steam penetrates into the items to be sterilized, it can form condensed water and release a large amount of latent heat, so that the temperature of the items rises rapidly, and the microbial proteins attached to the items are coagulated and die. However, its practical process is still not fully understood [1]. A number of studies have confirmed that the success of the sterilization process is influenced by a number of factors, such as the content of non-condensing gases, the load, the humidity of the packaging material, and others [2-4]. A case study on the orientation of phaco handpieces has shown that the vertical placement of its head during the pressure steam sterilization establishes the most favorable sterilization conditions [5]. It can be seen that the influence of the characteristics of medical instruments on the sterilization process cannot be ignored, but few researchers paid attention to the material of medical instruments. This research aims to monitor and analyze the pressure steam sterilization process of non-metallic medical instruments, and to explore the influence of different materials of medical instruments on the pressure steam sterilization effect.

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Experimental design

Two sets of non-metallic medical instruments with different materials and similar structures were selected, which were attached to wood material or silica gel material, and the metal medical instruments were set as the control group. Three sets of medical instruments were cleaned, disinfected, and checked before packaging. According to the packaging agreement of the hospital, medical textiles were used for packaging, and then the same pressure steam sterilizer (Balliman BRAND MST9618HS2) was used for sterilization. The pressure steam sterilizer has been verified before the experiment. The experimenter placed the test bag horizontally at the most difficult sterilization position of the sterilizer, that is, above the exhaust port. In each sterilization cycle, only one set of medical instruments was selected, and a full load was formed according to the sterilization requirements. The sterilization was carried out by the instrument procedure of pressure steam sterilizer, that is, the sterilization temperature was 134 ℃, the time was 240 seconds, the pressure was 201.7-229.3 kPa, and each set of medical instruments was sterilized 10 times.

The pressure steam sterilization process of each set of medical instruments was monitored in real-time by temperature and pressure detector (Big Dipper). The equipment had seven temperature probes and a pressure probe, each probe was connected to a 1.2 m long slender guide wire, and was equipped with a set of data analysis system. According to the surveillance standard for cleaning, disinfection and sterilization of CSSD, the test probe should be placed in the most difficult sterilization parts to determine the location of the three sets of medical instruments in this test: planar instruments which were placed on the surface, lumen instruments which were placed in the middle of the whole lumen, and complex instruments where were placed in the groove or gap. After sterilization, the obtained data list and the curve diagram were compared with the physical monitoring results of the sterilizer. The layout of the monitoring points of the three sets of medical instruments was shown in figs. 1-3.

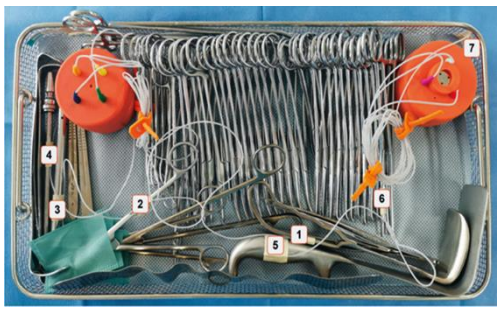

Figure 1. Layout of monitoring points for metallic medical instruments

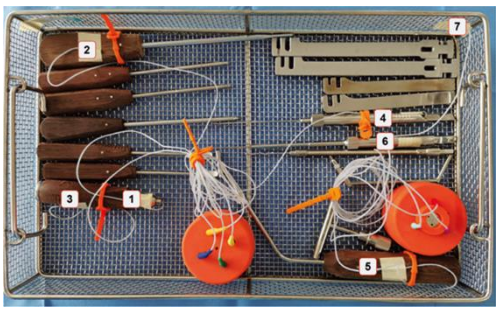

Figure 2. Layout of monitoring points of medical instruments attached with wooden material

The observation index was set according to the sterilization parameters in the instruction for use of medical instruments, and met the requirements of the industry standard on the sterilization temperature fluctuation range, the minimum sterilization time and the pressure range. The actual measured temperature needs to be 134-137 ℃, the shortest sterilization time is 240 seconds, and the pressure range is 201.7-229.3 kPa.

Results

Three sets of medical instruments were operated for 30 cycles, each group showed qualified physical monitoring, chemical monitoring and biological monitoring. The average temperature, time and pressure of each cycle met the requirements of the WS310.3 standard, except that some structures of non-metallic medical instruments attached with wood or silica gel materials, which had a delay in temperature rise, tab. 1. The results of this experiment showed that the metal medical instruments of the control group have reached the target value, that is, the sterilization temperature was 134 ℃ and the time was 240 seconds. The curves of seven monitoring points on the equipment tended to be consistent with the physical monitor-

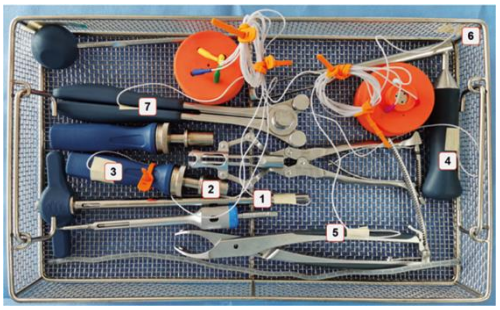

Figure 3. Layout of monitoring points of medical instruments attached with silica gel material

Table 1. Results of temperature delay time for pressure steam sterilization of non-metallic medical instruments [seconds]

Grouping	Monitoring Point	Target (S)	Cycle 1	Cycle 2	Cycle 3	Cycle 4	Cycle 5	Cycle 6	Cycle 7	Cycle 8	Cycle 9	Cycle 10
Metal instrument set (stainless steel)	1	240	0	0	0	0	0	0	0	0	0	0
	2	240	0	0	0	0	0	0	0	0	0	0
	3	240	0	0	0	0	0	0	0	0	0	0
	4	240	0	0	0	0	0	0	0	0	0	0
	5	240	0	0	0	0	0	0	0	0	0	0
	6	240	0	0	0	0	0	0	0	0	0	0
	7	240	0	0	0	0	0	0	0	0	0	0
Non-metallic instrument set (with wooden material)	1	240	–108	–122	–114	–119	–107	–124	-–13	–104	–117	–127
	2	240	0	0	0	0	0	0	0	0	0	0
	3	240	–98	–92	–96	–83	–94	–79	–86	–89	–91	–81
	4	240	0	0	0	0	0	0	0	0	0	0
	5	240	0	0	0	0	0	0	0	0	0	0
	6	240	0	0	0	0	0	0	0	0	0	0
	7	240	0	0	0	0	0	0	0	0	0	0
Non-metallic instrument set (attached with silicone material)	1	240	0	0	0	0	0	0	0	0	0	0
	2	240	–240	–240	–240	–240	–240	–240	–240	–240	–240	–240
	3	240	–29	–41	–37	–27	–38	–29	–30	–27	–31	–33
	4	240	0	0	0	0	0	0	0	0	0	0
	5	240	0	0	0	0	0	0	0	0	0	0
	6	240	0	0	0	0	0	0	0	0	0	0
	7	240	–88	0	0	0	0	0	0	0	0	0

ing curves of the sterilizer. For non-metallic instruments, such as medical instruments attached to wood (Point 1) or silica gel material (Point 2), especially those with a lumen structure, the internal monitoring points appeared temperature delay, resulting in a relative reduction of 104-240 seconds in sterilization time, and the internal temperature of silica gel material had been not risen to 134 ℃ until the end of sterilization time, which seriously fails to meet the standard requirements. There are huge security risks.

At the same time, the delay time of temperature rise on the surface of the instrument was shorter than that inside the lumen, the sterilization time of wooden instruments (Point 3) was relatively reduced by 79-98 seconds, and the sterilization time of silica gel devices (Point 3) was relatively reduced by 27-41 seconds. In addition, the experimenter found that, when the joint instrument made of silica gel (Point 7) was in the closed state, the temperature inside the instrument was difficult to rise, resulting in slow temperature rise and a relative decrease of 88 seconds in sterilization time. After the experimenter used the joint spreader on such instruments, there was no delay in temperature rise.

Discussion

Each sterilization cycle of the pressure steam sterilizer is an independent event, and its actual sterilization effect changes constantly throughout the day [3, 6]. Therefore, it is difficult to confirm whether the key parts of medical instruments with special materials and complex structures have been successfully sterilized [7]. According to the standard of Comprehensive guide to steam sterilization and sterility assurance in health care facilities, contact time, temperature and humidity are the necessary conditions for the success of pressure steam sterilization. Meeting specific temperature requirements of ANSI/AAMI ST 79-2017 (Comprehensive guide to steam sterilization and sterility assurance in health care facilities S1, 2017) is the key to ensuring the killing of heat-resistant bacteria. Meeting specific time requirements is to ensure that all items to be sterilized are in contact with steam at high temperatures for sufficient time [8]. At present, every pressure steam sterilizer has a temperature sensor, but it detects the temperature near the sterilizer exhaust (water) mouth, rather than the center of the package. In this study, the temperature and pressure detector was placed in the package to be sterilized, and the key parameters (temperature, time, pressure) of the whole sterilization process were monitored and recorded in real-time, which made the sterilization process visualized, and the potential risks could be found in time to ensure the sterilization effect.

Pressure steam sterilization mainly relies on the conduction of heat to realize the flow between gas and liquid, so that heat is conducted from one point to another. Stainless steel instruments belong to metal medical instruments, which are good conductors of heat and can rise to the target temperature in a relatively short time. Non-metallic medical instruments have relatively poor thermal conductivity, that is, they need more time to rise to the target temperature.

In this study, the temperature, time and pressure of metal medical instruments in the control group were within the qualified range, which created favorable conditions for sterilization. Non-metallic medical instruments such as wooden materials or silicone materials, especially those with a lumen structure, have different degrees of heating delay on the surface and inside the lumen, resulting in a relative reduction in sterilization time of 27-240 seconds, which cannot meet the relevant requirements for the sterilization of medical instruments of the WS310.3. The reason may be that when saturated steam contacts the surface of medical instruments, it will form condensate water on the surface of instruments whose temperature is lower than that of steam. Due to the poor thermal conductivity of special materials, a large

amount of steam is needed to keep it rising. In addition, the lumen structure of the instrument makes the special material wrapped on the outer surface of the instrument become the heat insulator around the lumen. Therefore, it is necessary to transfer and heat the inner surface of the lumen by steam penetrating the lumen of the instrument, forming condensation and releasing latent heat. When the medical instrument is placed horizontally, the condensation water formed in the lumen will not be discharged by gravity, which will prevent further condensation [5], resulting in slow warming. In addition, one study points out that the temperature of the temperature and pressure detector probe in the measurement will change the internal structure of lumen instruments to increase lumen internal surface area, improve the equipment itself through the characteristic of the steam [9], but this study shows that the instrument still exists up delay. This also reminds us of paying more attention in the future to the lumen of instruments made of special material package. As to whether the sterilization time should be extended to ensure the sterilization effect, it is still controversial and needs further study.

The sterilization effect of medical instruments depends on the contact condition of the sterilization agent with all surfaces within the specified time, so the correct placement of medical instruments can help to ensure the sterilization effect and prevent the damage of the instruments [9]. The sudden temperature change or short temperature oscillation will give an instantaneous effect on the sterilization process. A mathematical model for analysis of the temperature response [10, 11] is also very needed in future, especially for the low-temperature sterilization [12, 13] and the dry sterilization [14].

In this study, it was found that if the joint of the instrument attached by the silica gel material was in a closed state, the temperature rise delay was very easy to occur, and the sterilization time was only maintained for 152 seconds, while the metal medical instrument of the same type was not affected by the closed state. The analysis may be because that when there are many instruments in the package, it is easy for the instruments to move in the package during the loading process, resulting in a closed state of the instrument joints. The silica gel material is more likely to form a closed space than metal instruments, which is not good for the penetration of steam on the inner surface of the handle, leading to heating difficulty. After the intervention of experimenters, there was no heating delay in the last nine cycles. It is recommended to use a joint spreader when placing joint instruments attached to special materials to ensure steam penetration effect.

The rapid development of minimally invasive technology, along with the increasing number of medical instruments with special materials, *e.g.* nanoscale membranes [15, 16], complex structures, and sophisticated structures, poses new challenges for ensuring the sterilization effect. This study found that non-metallic medical instruments, such as those attached to wood or silicone material, especially the medical devices with lumen structure, need to be paid more attention by the staff of CSSD. The structural characteristics of the instruments should be combined to create favorable sterilization conditions. At the same time, it is suggested that medical instrument manufacturers should fully evaluate whether the sterilization conditions meet all the surfaces of medical instruments in the process of developing these medical instruments. This study also has some limitations, in the next step, the sample size will be expanded to further monitor the qualified sterilization conditions of non-metallic medical instruments, to provide guidance for future work.

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