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Case study on the orientation of phaco hand pieces during steam sterilization processes

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SUMMARY

Background: Steam sterilization is an essential part of infection prevention. The literature shows that sterilization of medical instruments containing channels is not trivial. Phaco hand pieces have a simple configuration: a device contains a channel with a constant radius. No literature was found indicating whether the sterilization conditions on the inner surface of a phaco hand piece are influenced by the orientation of the hand piece.
Aim: To determine whether the orientation of a phaco hand piece influences the results of a sterilization process of this device.
Methods: A qualitative case study, including experiments, is performed with a protocolled combination of steam sterilizer, process, phaco hand piece, orientation of the phaco hand piece, and wrapping.
Findings: In this specific case, the orientation of the hand piece influenced the result of the steam sterilization process; in vertically (upright) oriented phaco hand pieces with free water drainage, sterilization conditions are reproducibly established. In the same process, in horizontally oriented or vertically oriented hand pieces without free drainage, these conditions are not established in a reproducible way.
Conclusion: In the investigated combination of sterilizer, process, load, loading pattern and wrapping, phaco hand pieces have to be oriented vertically (upright) with free water drainage to obtain steam sterilization conditions on the inner surface. It is likely that instruments with comparable configuration and dimensions will yield comparable results. It is therefore recommended that this issue is considered during the development of medical instruments and during performance qualifications of such instruments.

Introduction

Sterilization of medical devices is an essential part of infection prevention.[1,2] The most applied sterilization method in hospitals is steam sterilization and is performed in steam sterilizers. Criteria for surface steam sterilization are specified in the literature and international standards: saturated steam

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Figure 1. Schematic representation of a horizontally oriented phaco hand piece. The channel is used for the removal of a cataract out of the patient's eye. The hand piece chassis, represented by the black lines, can be manufactured from different materials, e.g. stainless steel, titanium, or alloys. In the compartment, hardware such as electronics to control the drill are present. In this compartment, air may also be present. The length of a channel is typically of the order of 0.15 m, whereas the length of the technical compartment is 0.10 m. The inner radius of the channel is of the order of 0.0005 m (0.5 mm), whereas the outer diameter of the hand piece is of the order of 0.015 m (15 mm). For the measurements, a thermocouple (type K) is fixed in the middle of the channel.

at a defined temperature–time combination.[3–7] An example of a typical steam sterilization process is saturated steam at 134°C for 3 min.[3] Creating these sterilization conditions on all surfaces of instruments depends on several factors, such as the sterilizer, the process, the load, the loading pattern, and the wrapping.[4] In particular, creating steam sterilization conditions on inner surfaces of hollow instruments appears to be far from trivial.[8,9] Here we report a case study demonstrating that the loading pattern (orientation) of a phaco hand piece influences the result of the sterilization process in this instrument.

To create steam sterilization conditions on inner surfaces of instruments, the initially present air has to be replaced by steam. The steam has to penetrate into the cavities of the instruments. A simple configuration of a cavity is a channel with a constant radius. In the literature it is reported that the orientation (angle with respect to the vertical direction) of a channel influences the penetration of steam in that channel.[10,11] This indicates that narrow channels with two open ends should be oriented upright during a sterilization process. However, in the applicable standards for steam sterilization, we have not found adequate methods or instructions to position or orient channelled medical instruments during steam sterilization processes.[7,12–17]

In practice, it is often observed that narrow channels are oriented horizontally (Figure 1). This occurs because many instruments containing a channel cannot be oriented upright during a sterilization process, e.g. in the upright orientation the instruments do not fit into the sterilizer chamber, or the loading facilities of the sterilizer (trays) cannot facilitate this orientation.

Based on the information in the literature and observations in practice, we found it worthwhile to perform a case study with three different phaco hand pieces (Figure 1). A phaco hand piece, used in ophthalmic surgery, was chosen because it has a simple configuration of a channel with constant radius and two open ends.

Methods

Methodology

As specified in the hospital wrapping protocol, each individual hand piece was placed in a separate tray/container and wrapped in a sterilization pouch. One side of this pouch consisted of paper and the other side of a transparent foil

Figure 2. Wrapping and loading of the phaco hand pieces. The phaco hand pieces are fixed in a tray/container. The tray/container is wrapped in a pouch. Because the thermocouple has to be led into the pouch, the pouch is closed by folding and taping instead of heat-sealing. The left picture shows an example of two vertically oriented and three horizontally oriented phaco hand pieces in a full sterilization load. In case of a vertical orientation, the thermocouple wire is led into the channel via the top end of the channel. The right picture shows an example of three vertically and two horizontally oriented hand pieces and the position of the load in the sterilizer.

(Figure 2). The pouches complied with the applicable standards.[18,19] Furthermore, the hospital protocol specified that the hand pieces had to be oriented vertically (upright) during sterilization. The tray/container had to be fixed in the net to stabilize its orientation during the sterilization process. For our experiments, hand pieces were positioned in three different ways: vertically with free drainage via the open end of the channel, horizontally, laying on a wrapped instrument set, and vertically without free drainage via the open end of the channel. In each process, a full load was composed according the hospital protocol (Figure 2). This load was placed in a production sterilizer and processed in accordance with the standard process of the facility. The internal dimensions of the sterilizer were approximately 69 × 66 × 133 cm. Its process parameters can be deduced from Figure 3. In the middle of the channels, thermocouples were fixed (Figure 1). Where the phaco hand piece was oriented vertically, the thermocouple was inserted via the open end at the top to ensure free water drainage.

As specified in the hospital protocol, a steam sterilization process with a plateau period of about 4 min (240 s) at 134°C was used. During the process the temperatures measured in the middle of the channels of the phaco hand pieces and the pressure in the sterilizer were recorded (Figure 3). The pressure measurement was used to calculate the theoretical temperature.[6,7,20]

Figure 4 shows the plateau period of the process: 134°C for about 4 min (240 s). The requirements specified for the temperature in the standards were used to judge the measurements. To demonstrate reproducibility, 35 measurements are summarized in Table I.

Using a theoretical approach, possible explanations for the results of the experiments are discussed.

Phaco hand pieces

For the measurements, one type of three different brands of hand pieces was used. In practice, many brands and types are commercially available. Using a theoretical approach the condensate formation can be estimated. For this estimate, dimensions and physical properties are needed. Based on information from the phaco hand piece manufacturers and from product specifications, typical properties of hand pieces are collected and presented in Table II.

The lower the condensate formation in the channel, the more favourable the sterilization conditions are, as will be shown below. In the calculations, all properties were chosen in favour of a positive result for sterilization. For example, the lowest weight specification received from manufacturers was 0.16 kg, whereas we used 0.15 kg. Also, a lower total heat capacity was used instead of the specified value for the various materials.

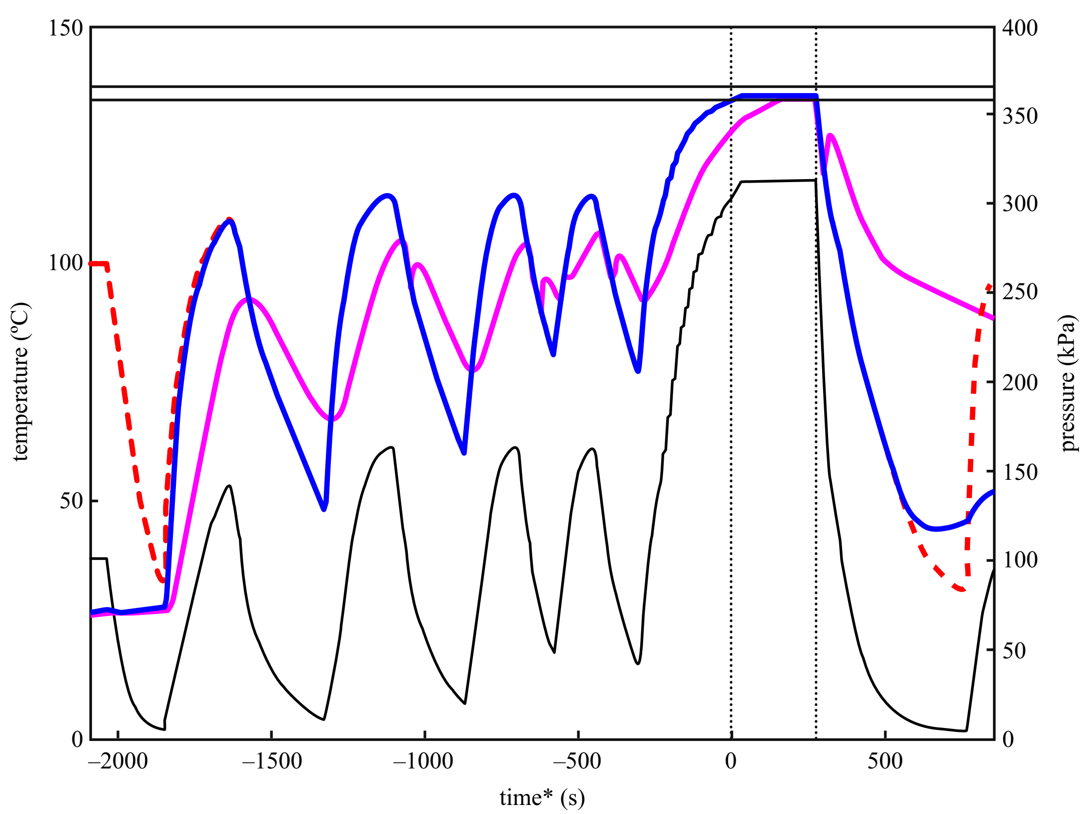

Figure 3. A measurement in a vertically and in a horizontally oriented phaco hand piece in a typical production process used in this study. The vertical dotted lines mark the start and the end of the plateau period.[7] The black curve represents the pressure of the process and the dashed red curve the theoretical temperature calculated from the pressure.[4,20] The blue curve represents the temperature measured in the middle of the channel of the vertically (upright) oriented hand piece, whereas the pink curve presents the temperature in the middle of the channel of the horizontally oriented hand piece.

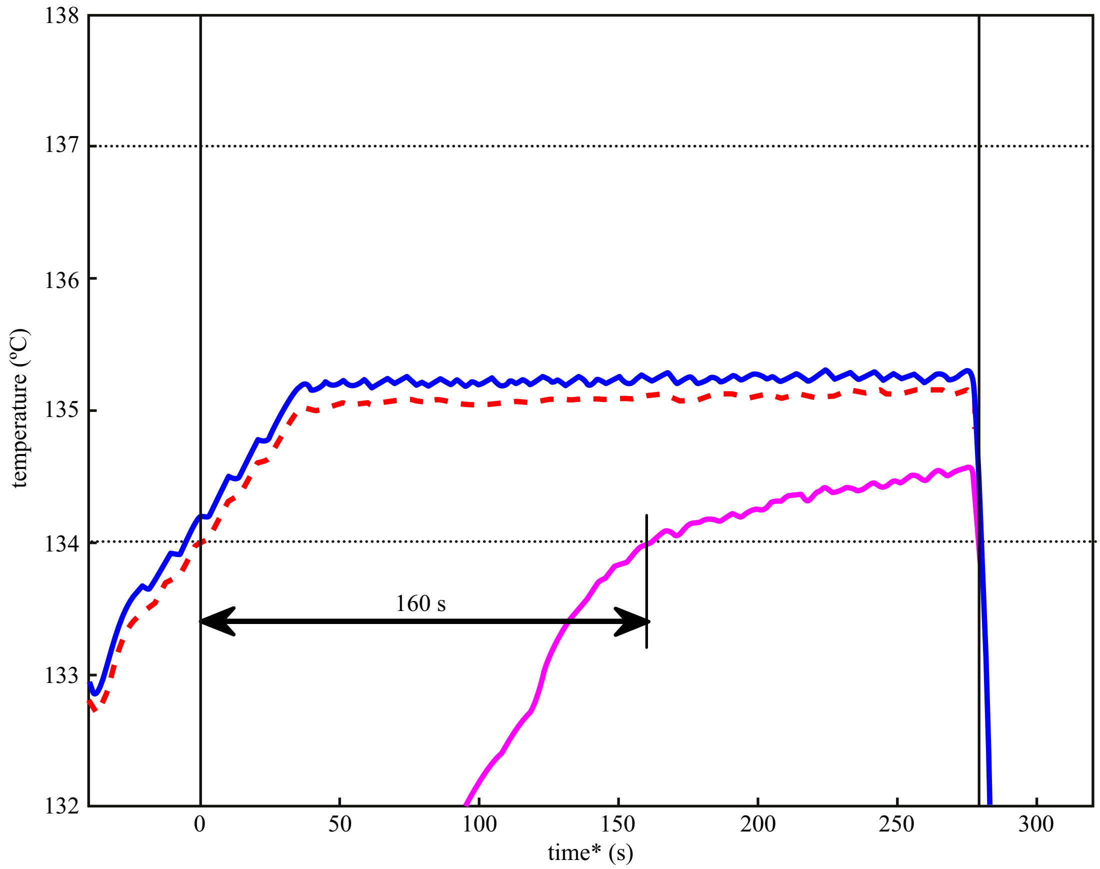

Figure 4. Measured temperatures in the middle of the channels of two phaco hand pieces during the plateau period.[7] The blue curve represents the vertically (upright) oriented and the pink curve the horizontally oriented hand piece. In this measurement the middle of the horizontally oriented hand piece reaches the aimed temperature of 134°C only after 160 s (2.7 min), whereas the temperature in the middle of the channel of the vertically oriented hand piece follows the theoretical temperature (dashed red curve) almost instantaneously.

Measuring equipment

Measurements in the middle of the channel of the phaco hand piece were performed with a thermocouple type K. The cross-section of the thermocouples including insulation was 0.2 mm^2 per wire. With two wires and the dimension of the channel of the phaco hand piece (Table II) this corresponded to

Table I
Results of 35 measurements in the middle of a phaco hand piece compared with the criteria in the standard EN 285

Orientation of phaco hand piece	Brand A		Brand B		Brand C		Total	
	Pass	Fail	Pass	Fail	Pass	Fail	Pass	Fail
Horizontal	–	11	–	3	–	2	–	16
Vertical	11	–	1	–	1	–	13	–
Dropped	–	3	–	1	–	2	–	6

'Horizontal' indicates that the phaco hand piece was lying horizontally in the load (Figure 2). 'Vertical' indicates that it is orientated vertically and that the condensate has a free drainage out of the channel of the hand piece. 'Dropped' indicates that the phaco hand piece is positioned vertically but the open end of the channel is resting on the edge of the tray/container. All results are reproducible, independent of the brand of hand piece.

Table II
Dimensions of a phaco hand piece and properties used for the calculations

Hand piece variables	Values
Dimensions	
Length of channel in hand piece	0.15 m
Inner radius channel	0.001 m
Weight of hand piece	0.15 kg
Heat capacities material of hand piece	
Titanium	520 J/(kg K)
Stainless steel	480 J/(kg K)
Most (fictive) favourable value	380 J/(kg K)
Steam properties[20]	
Latent heat of steam (at 373 K)	2.25×10^6 J/(kg K)
Density of steam (at 373 K)	0.598 (kg/m^3)
Volume ratio between steam and water	1700

All dimensions and properties are chosen based on information collected from the manufacturer and from product specifications. Properties used for calculations have been chosen in favour of a positive sterilization result, which corresponds to the smallest amount of condensate.

12.7% of the surface of the cross-section of the channel, and 6.4% of its volume. To measure the pressure, a pressure transducer (JUMO pTRANSp30, Jumo GmbH & Co. KG, Fulda, Germany) was mounted on the sterilizer. The system used to record the temperatures and pressure was a CDAS 101 (Causa BV, Eindhoven, The Netherlands). Shortly before and after the measurements, the measurement system was calibrated. It complied with the requirements specified for measuring equipment in the standard EN 285.[7]

Results

Figure 3 shows a typical result of measurements in the middle of a vertically and a horizontally oriented hand piece. In the graph, the pressure, the theoretical temperature, and the temperature in the middle of the hand pieces are plotted.[6,7,20] A detailed plot of the plateau period, including the actual sterilization phase, is presented in Figure 4.[7] These values show that the temperature in the horizontally oriented hand piece reached the aimed sterilization temperature (134°C) 160 s after the theoretical temperature has reached the sterilization temperature. This is in contrast to the vertically (upright) oriented hand piece. In this case the temperature profile of the hand piece was almost identical to the profile of the theoretical temperature.

In total, 35 measurements were performed (Table I). The results were reproducible and independent of the brand of hand piece. Only the orientation appeared to be decisive for the result. All 15 horizontally oriented phaco hand pieces showed a delay in reaching the aimed sterilization temperature. This delay varied from 70 to 240 s (not reaching sterilization temperature at all). With these delays the requirements in the literature, 134°C for ≥180 s (3 min), are not met.[3,4] For instance, the longest plateau period was 240 s (4 min) minus 70 s, leaving 170 s. Also the temperature requirements in the applicable standard EN 285 were not met.[7] By contrast, all 13 vertically oriented hand pieces fully met the requirements for surface steam sterilization.[3,4,7] In these cases the delay of reaching 134°C was of the order of seconds.

'Dropped' hand pieces are vertically positioned, but during the process they 'drop' out of the fixing and rest with the open end of the channel on the edge of the tray/container. This blocks the open end of the channel and reduces or stops free drainage of condensate. To demonstrate that free drainage is of major importance, 'dropped' phaco hand pieces were simulated by letting the vertically orientated phaco hand pieces rest on the open end of the channel. In this situation, the open end of a channel was partly or completely closed by the surface of the edge of the tray/container. In six out of six cases, the temperature profile appeared to be comparable to that of a horizontally positioned hand piece (Table I).

Upon warming a typical phaco hand piece to 134°C, the amount of condensate formed can be estimated with the information presented in Table II, using the equation:

$$V_{cd} = \frac{m_{st}}{\rho_{st}\Gamma_{st,cd}} = \frac{m_{ph}C_{ph}\Delta T}{L_{st}\rho_{st}\Gamma_{st,cd}} \qquad (1)$$

In this equation the subscripts *st*, *cd*, and *ph* denote steam, condensate, and phaco hand piece, respectively. *V* is the volume (m^3), *m* the mass (kg), ρ the density (kg/m^3), Γ the volume ratio between steam and condensate, *c* the heat capacity [J/(kg K)], ΔT the temperature difference between steam and hand piece (K), and *L* the latent heat [J/(kg K)]. Assuming a temperature difference for warming up the hand piece of 110 K (sterilization temperature minus the environmental temperature) yields 2.74×10^{-6} m^3 of condensate.

The channel of a typical phaco hand piece has a volume of 4.71×10^{-7} m^3. This means that to fill the channel of the hand piece completely with liquid, ~17% of the condensate is needed. This 17% condensate corresponds to 17% of the energy needed to warm up the hand piece. As long as a surface is colder than the steam, condensate will be formed at this surface.[21,22] Because of the construction of the hand piece (Figure 1) the compartment around the channel will act as thermal insulator. Therefore the energy to warm up the inner surfaces has to be transported by steam penetrating into the channel of the hand piece. On the colder inner surface, the steam will condense, releasing its latent heat. Because of the insulating compartment and the construction of the phaco hand pieces, >17% of the total energy may be needed to warm up the inner surfaces. As mentioned above, the corresponding amount of condensate will exceed the volume of the channel. In a horizontally oriented hand piece, the condensate is not drained out of the channel by gravity. Consequently, the channel may be filled completely with condensate. This will block further condensation, resulting in a slow warming up, as measured experimentally (Figures 3 and 4). It cannot be excluded that when condensate is formed very fast and is not drained out of the channel, droplets may form that block the channel (Figure 5). Initially present and relatively cold air can be entrapped between two of these droplets. Such an air pocket will act as a thermal insulator. Also in this case, steam has only limited access to the inner surfaces. Consequently, the temperature increase in the channel will show a delay and steam sterilization conditions are not established in this process.

By contrast, in a vertically oriented hand piece the formed condensate can be drained out of the channel by gravity. This allows the steam permanent access to the inner surfaces of the channel and the warming up is following the theoretical temperature of the process (Figures 3 and 4).

In case of a 'dropped' phaco hand piece, similar effects will take place as for a horizontally oriented hand piece, because

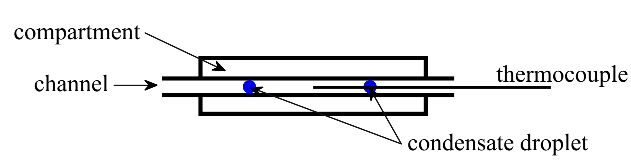

Figure 5. Schematic representation of a horizontally oriented phaco hand piece in which condensate droplets are blocking the channels. The volume of gas (air) enclosed between the droplets will have a lower temperature than the steam, because steam cannot access the inner surfaces. Upon pressure changes, the droplets will move in opposite directions with respect to each other. The enclosed gas will only be compressed or decompressed. Consequently, the energy to increase the temperature can only enter by heat conduction via the droplets or via the outer wall of the hand pieces through the chassis and the compartment. This heat transfer mechanism is much less efficient than steam condensation.

the closed end of the channel will reduce the drainage or even completely block it. Consequently, the channel will be partly or completely filled with condensate.

Discussion

Requirements for steam sterilization conditions are specified in the literature and standards.[3,4,7,15] If these requirements are applied to the specific combination of sterilizer, process, phaco hand piece, orientation of the hand piece, and wrapping studied here, it cannot be claimed that horizontally oriented and vertically but 'dropped' phaco hand pieces are sterile after the process. For vertically (upright) oriented hand pieces with a free drainage of the condensate, processed at the same conditions, it can be claimed that they are sterile.

The difference between the temperature curves of the vertically (upright) and horizontally oriented hand pieces can be explained by condensate formed in the channel of the hand piece during the process. In vertically oriented hand pieces, gravity drains condensate that is formed on the inner wall of the channel out of the channel. This provides permanent access of the steam to the colder places of the inner surface and condensing steam can release its energy to that surface. Consequently, the temperature can follow the temperature of the sterilization process, sterilization conditions are met, and sterility can be claimed.

In horizontally oriented hand pieces, gravity cannot drain the formed condensate out of the channel. In this case, the formed condensate can fill up the complete channel, or, if condensation is fast enough, an air pocket can be formed between two condensate droplets. In both cases, the temperature in the channel will increase more slowly and sterilization conditions may not be established. For vertically positioned hand pieces with reduced or blocked drainage, e.g. because of 'dropping', the same effects are present as in the horizontally positioned hand pieces. Thus, for this orientation and position also, sterilization conditions may not be established.

Phaco hand pieces come in many brands, variations, and materials. The measurements reported here include one type of three different brands of phaco hand pieces and only one standard process. The results were found to be independent of the brand of hand piece. It is the aim of the present quantitative case study to reach general conclusions and not to qualify manufacturers of phaco hand pieces or steam sterilizers. Many factors can influence the final result of sterilizing phaco hand pieces. Among these are the material of the inner surface of the channel, the radius of the channel, and the pressure changing rate in the process. This confirms that for steam sterilization the combination of sterilizer, process, load (phaco hand pieces), loading pattern (orientation) and wrapping is essential. Consequently, during the development and qualification of sterilization of phaco hand pieces, these factors have to be considered and studied.

In conclusion, it is generally accepted that the result of a sterilization process depends on the combination of sterilizer, process, load, loading pattern and wrapping. In this case study, it is demonstrated that horizontally oriented and 'dropped' phaco hand pieces are not sterilized. In order to ensure effective and reproducible sterilization of phaco hand pieces, the hand pieces have to be oriented vertically and must have free drainage.

Many factors may influence the final result of sterilizing phaco hand pieces. These factors may also be applicable to other (heavy) channelled and complex instruments. It is therefore recommended that during development of these devices, but also during performance qualifications, studies are performed to assess whether, for the actual combination of sterilizer, process, load (device), loading pattern (device orientation), sterilization conditions are met on all surfaces.

It is also recommended that these findings are considered in the standards for (steam) sterilization.[7,12–17]

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