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Second case study on the orientation of phaco hand pieces during steam sterilization

Sir,

Steam sterilization is the most commonly used method to sterilize medical devices in hospitals.[1,2] In the last decades, complex instruments (minimal invasive surgery) with hinges and (narrow) channels have been introduced. These developments challenge the establishment of steam sterilization conditions on the inner surfaces of devices with narrow channels, as reported in the literature.[3]

A previous study demonstrated that the orientation of a phaco hand piece influences the result of the sterilization process.[4] It was reported that sterilization conditions are established reproducibly for vertically (upright) oriented phaco hand pieces with free water drainage. However, in daily practice, vertically oriented medical devices may lead to practical problems when loading sterilizers. Therefore, it is of interest to study whether sterilization conditions on the inner surfaces of hand pieces can be established reproducibly with other orientations (angles from 0° to 90°). Additionally, it is interesting to determine whether different sterilizers and processes can establish sterilization.

In this study, each individual phaco hand piece was placed in a ½ DIN basket and wrapped according to the hospital protocol with meatex (SSMMS) regular and heavy duty wrapping material (Interster, Wormerveer, The Netherlands). The phaco hand pieces were fixed in the basket and placed on a specially developed construction in five different angles (0°, 30°, 45°, 60° and 90°). The load was placed in a Sanamij type SAR 6.6 sterilizer with internal dimensions of approximately 116 × 62 × 60 cm (Rotterdam, The Netherlands). Thereafter, the load was processed according to the hospital protocol and processes (Figure 1). During the process, the temperature inside the phaco hand piece was measured as in the previous study.[4] Three brands of phaco hand pieces were used, and will be referred to as Brands A, B and C. Overall, 43 measurements were performed. EN 285 specifies that all measured temperatures should reach sterilization temperature (≥134 °C) at the start of the sterilization phase.[2] The results (Figures 2 and 3) show that 16 and 27 measurements met and failed this requirement, respectively. The hand pieces with 60° and 90° orientation complied better with the standard than the hand pieces with horizontal (0°), 30° and 45° orientation. All of the Brand C hand pieces reached sterilization temperature at 60° and 90° orientation.

Figure 3 presents the temperatures measured in the plateau period of the sterilization cycle in nine horizontally oriented hand pieces. Only one hand piece reached the sterilization temperature at the same time as the theoretical temperature. The time that each phaco hand piece has reached the sterilization temperature (134 °C) varied from 0 to 210 s. In four cases, the sterilization temperature was never reached.

The results of this study are in line with the findings of the previous study.[4] The failure rates were higher among horizontally and 30° oriented hand pieces compared with those

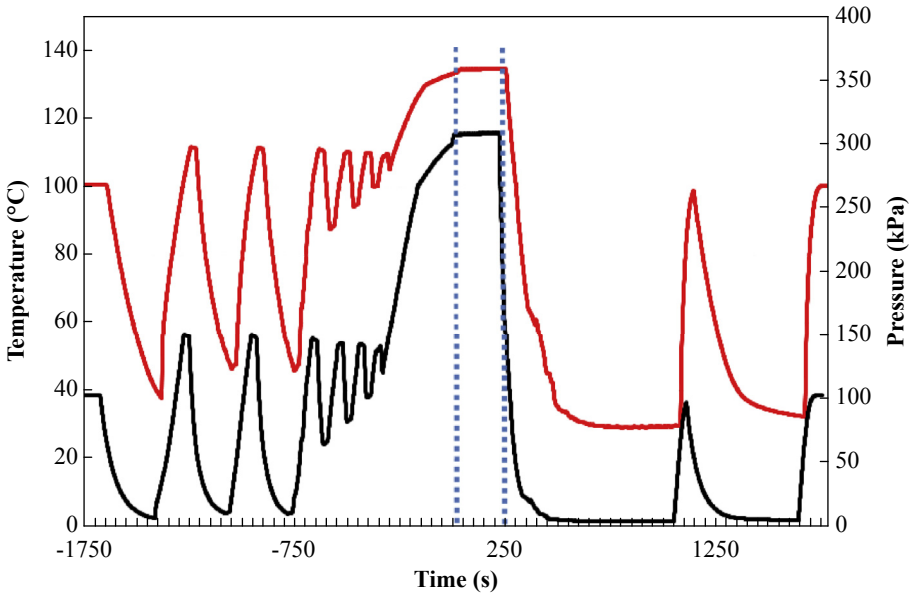

Figure 1. Process used in the experiments. Pressure is represented by the black curve and theoretical temperature is represented by the red curve. The process includes a fractionated vacuum phase, followed by a plateau period of 3.5 min at 134°C (indicated with dashed lines) and a drying phase.[2]

oriented at larger angles (see Figure 2). A more detailed analysis of the results shows that phaco hand pieces oriented at 60° and 90° reached the sterilization temperature much faster than the hand pieces oriented horizontally and at 30° and 45°. This supports the theory that condensate blocks the channel due to lack of drainage forced by gravity.[4]

In the previous study, a 100% failure rate was found in horizontally oriented phaco hand pieces, and a 100% pass rate was found in vertically oriented hand pieces. In this study, 89% failed and 57% passed, respectively. The measurements in this study were performed in a different sterilizer using a different process and wrapping compared with the previous study,[4] and these factors obviously influenced the success of sterilization.

Brand C hand pieces complied with the requirement (134 °C for at least 3 min) in eight out of 12 (67%) cases, while Brand A hand pieces complied in three out of 12 (25%) cases and Brand B hand pieces complied in five out of 19 (26%) cases (Figure 2). All of the Brand C hand pieces met the requirement at 60° or 90°, but Brand A and B hand pieces did show fails at these orientations. This may be explained by the differences in dimensions and physical properties between the brands, such as heat capacity and weight.

In conclusion, this study demonstrated that the orientation and design of phaco hand pieces are essential factors in establishing sterilization conditions on the inner surfaces. In combination with the previous study, it is not possible to define a preferred orientation for sterilization of a phaco hand piece.[4] Nevertheless, it is more likely that sterilization conditions will be met in vertically oriented hand pieces. Furthermore, is it confirmed that the result of a sterilization process is influenced

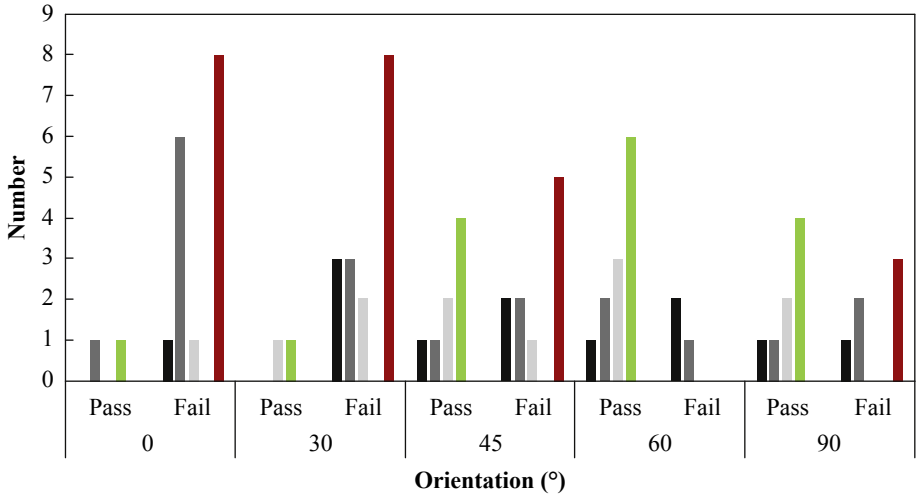

Figure 2. Results of 43 temperature measurements in the centre of phaco hand pieces in five different angles. Measurements were taken in three different brands (A, B and C). Brand A, black bars; Brand B, dark grey bars; Brand C, light grey bars; accumulated pass results, green bars; accumulated fail results, red bars.