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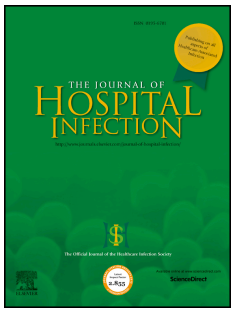

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Investigating steam penetration using thermometric methods in dental handpieces with narrow internal lumens during sterilizing processes with non-vacuum or vacuum processes.

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running title: Steam penetration into dental handpieces

Summary

Background: Dental handpieces are required to be sterilized between patient use. Vacuum steam sterilization processes with fractionated pre/post-vacuum phases or unique cycles for specified medical devices, are required for hollow instruments with internal lumens to assure successful air removal. Entrapped air will compromise achievement of required sterilization conditions. Many countries and professional organisations still advocate non-vacuum sterilization processes for these devices.

Aim: To investigate non-vacuum downward/gravity displacement, type-N steam sterilization of dental handpieces, using thermometric methods to measure time to achieve sterilization temperature at different handpiece locations.

Methods: Measurements at different positions within air turbines were undertaken with thermocouples and dataloggers. Two examples of commonly used UK benchtop steam sterilizers were tested; a non-vacuum benchtop sterilizer (Little Sister 3, Eschmann, UK) and a vacuum benchtop sterilizer (Lisa, W&H, Austria). Each sterilizer cycle was completed with three handpieces and each cycle in triplicate.

Findings: A total of 140 measurements inside dental handpiece lumens were recorded. We demonstrate that the non-vacuum process fails (time range 0-150 seconds) to reliably achieve sterilization temperatures within the time limit specified by the International standard (15 seconds equilibration time). The measurement point at the base of the handpiece failed in all test runs (n=9) to meet the standard. No failures were detected with the vacuum steam sterilization type B process with fractionated pre-vacuum and post-vacuum phases.

Conclusion: Non-vacuum downward/gravity displacement, type-N steam sterilization processes are unreliable in achieving sterilization conditions inside dental handpieces and the base of the handpiece is the site most likely to fail.

Keywords: dental handpieces, steam sterilization, non-vacuum sterilizers, vacuum sterilizers, dental infection control, sterilization failure, thermocouples, downward/gravity displacement, type-N sterilizing process, sterilization type B process, fractionated pre-vacuum and post-vacuum phases, hollow instrument, sterility assurance.

Introduction

Dental handpieces become contaminated externally and internally following patient treatment (1-5). Clinical evidence for cross infection events is difficult to assign to a particular incident due to the fact that infections are difficult to trace back to a dental treatment (6), but there are reports of incidents linking inadequate decontamination of dental instruments to Hepatitis B transmission (7). Technical evidence for the necessity for air removal from lumens has been provided by many studies investigating steam penetration into lumens of medical devices in a laboratory setting (8,9). International and Regional standards require that hollow instruments such as dental handpieces should be sterilized using a vacuum steam sterilization type B process with fractionated pre-vacuum and post-vacuum phases, due to their complex construction and internal lumens that can lead to trapped air comprising steam penetration. This is also recommended by manufacturers of sterilizers and dental handpieces alike(10,11). However, in many countries including UK dental practices non-vacuum downward/gravity displacement, type-N sterilizing processes are still commonly used (12-14). Steam penetration into lumens and subsequent temperature changes can be measured using thermocouples (TC), which are routinely used during the commissioning and validation of steam sterilizers (15-19).

The aim of this study was to investigate steam penetration and time to reach sterilization temperature inside dental handpieces at three locations under non-vacuum downward/gravity displacement, type-N and vacuum steam sterilization type B process with fractionated pre-vacuum and post-vacuum phases.

Material and Methods

Sterilizers

Two different sterilizers were included in the study. A non-vacuum downward/gravity displacement, type-N benchtop sterilizer (Little Sister 3, Eschmann, UK) and a vacuum steam type B process with fractionated pre-vacuum and post-vacuum benchtop sterilizer (Lisa, W&H, Austria).

Handpieces

The dental handpieces (HP) used to monitor thermometric results were new dental air turbines (Synea TA-98 C LED, W&H, Austria).

Thermocouples and data loggers

Three types of thermocouples (TC) were used for thermometric measurements within the handpiece lumens. For air channel (internal diameter 2.3 mm) measurements in the non-vacuum downward/gravity displacement, type-N sterilizer type T thermocouples (Class 1 IEC, Flat Twin, cross section 2 mm x 1 mm, Omega, Stamford, UK) were used, while thin type T TC's (D = 0.8 mm) (Omega, Stamford, UK) were used for measurements in the air and spray channel (D=0.9mm). For air channel measurements in the vacuum sterilizer, data loggers with a flexible Teflon sensor (D = 2 mm) (Ellab, Denmark) were utilized (dataloggers were calibrated in-house by Ellab). The cut-off value for sterilization equilibration time between the chamber and handpiece lumen locations to reach 134°C was 15 seconds (15). Every ten cycles the type T and thin TC's were calibrated using a hot block (Ametek, UK) and the pressure sensor was calibrated using a pressure calibrator (Druck, UK). Both instruments having been validated by the United Kingdom Accreditation Service (UKAS). A data logger (Anville 825) and EaziVal SE software (Anville, UK) were used to record and analyse the acquired data. New TC ends were made every three cycles and readings were recorded at a rate of one measurement/sec and displayed onto an e-graph Y-axis units = temperature (°C)/pressure (bar) and x- axis units = time (min).

Test procedure

The non-vacuum downward/gravity displacement, type-N and vacuum processes were monitored by recording temperature and pressure (Ellab pressure datalogger) measurements. Three dental turbines (TA-98 C LED, W&H) were dismantled and type T TC were carefully placed by measuring in different locations (A, B and C) along the drive air channel (D = 2.3 mm) (Figure 1). Position A & B were located 10 mm & 35mm from the turbine end respectively while location C was located 45mm from the coupling end. After reassembling, handpieces were put through a non-vacuum downward/gravity displacement, type-N sterilization cycle (Little Sister 3, Eschmann). Experiments were performed in triplicate. Bowie and Dick test packs (BDT, Browne Ltd, UK) and the helix process challenge device (Browne Ltd, UK)

were used as controls for steam penetration. The BDT was carefully opened using a scalpel and TC were placed in three locations (top, centre and bottom with 100 paper sheets between locations). The test pack was re-sealed again using autoclave tape (3M, UK). A non-vacuum downward/gravity displacement, type-N sterilization cycle was performed. Experiments were repeated using thin TCs in order to record temperature in the air channel (D=2.3 mm) in locations A, B and C. A further three handpieces were used to measure temperature in location C of the spray channels (D=0.9 mm). Additional investigations using the wireless data loggers (Ellab, D=2 mm, Teflon) were used to monitor temperature in different locations of the turbine (drive air channel) in a vacuum type B process with fractionated pre-vacuum and post-vacuum sterilization cycle (Lisa 517, W&H, Austria) as a comparison to the non-vacuum downward/gravity displacement, type-N sterilizing process. Ellab's ValSuit Basic software was used for analysing the recorded data. As a control the BDT was used and experiments were performed in triplicate as a minimum.

Determination of the time difference between the chamber and the inside of the handpieces reaching sterilization temperature (134°C) was recorded, as shown in an example (Figure 2). Three sets of experiments were performed. For the first set, type T thermocouples (TC) were used. For the second set of experiments thin (D = 0.8 mm) type T TC were used and the third set of experiments were performed using wireless data loggers (Ellab, Denmark). Statistical analysis was performed using independent sample T-test, comparing different process/location groups using SPSS Statistics Sofrware (IBM).

Results

A total of 140 measurements inside dental handpiece lumens were recorded (Table 1). The time/temperature recording results show that it takes longer to achieve sterilizing temperature (134℃) inside hand pieces with a non-vacuum downward/gravity displacement, type-N sterilizing process. Location A shows a temperature lag of 2 - 33 sec compared to the chamber temperature, while sterilizing temperature in locations B and C were delayed by 0 - 23 and 2 - 150 sec, respectively. Recordings using the thin TC in different locations of

the handpieces showed time differences to the chamber of 4 – 52 sec in location A, -2 – 34 sec in location B and 5 – 27 sec in location C. Temperature traces from inside the spray channels showed a temperature lag of 4 - 78 sec compared to the chamber.

The control BDT temperature time recordings showed that the centre of the test pack did not reach sterilization temperature (data not shown) during the non-vacuum downward/gravity displacement, type-N sterilizing process. All thermometric measuring devices found that for the BDT controls, inside the pack temperatures did not reach sterilizing temperature during the non-vacuum downward/gravity displacement, type-N sterilization cycle and all locations achieved sterilization temperature in the vacuum sterilization process.

Thermometric results using data loggers in dental handpieces in the vacuum sterilization process did not differ from the results acquired using the BDT in a vacuum sterilization process. Using a vacuum steam sterilization type B process with fractionated pre-vacuum and post-vacuum cycle (Lisa, W&H) thermometric measurements showed a time difference of 0 - 3 sec between the inside of handpiece (location A) compared to the chamber of the sterilizer, 1 – 3 sec in location B and -1 - 3 sec in location C. No significant differences were observed between locations A, B and C. Statistical analysis showed that the measured time delay in location C using a non-vacuum downward/gravity displacement, type-N sterilizing process is significantly higher ($p=0.001$) than all other location/TC combinations and fails to meet an equilibration time to reach 134°C of 15 seconds compared to the chamber temperature.

Discussion

These investigations of steam penetration into lumens demonstrated that saturated steam penetrates lumens more successfully in vacuum steam sterilization type B cycles and that non-vacuum downward/gravity displacement, type-N sterilizing processes are unreliable and in line with previous reports (20). The key prerequisite for saturated steam and to achieve the relatively large release of energy required for sterilization, is that water is at the boiling point, where a change of phase (saturated steam/gas to water/liquid) can occur. The boiling point of a liquid is reached when the

vaporization pressure of the liquid exceeds the surrounding air pressure. The boiling point varies according to air pressure. It is important therefore, that the air first be removed from the sterilizer chamber and from all products intended to be sterilized, even if microscopic the remaining air pockets will prevent the steam from direct contact with the items and surfaces to be sterilized. The remaining air pockets will be heated by the surrounding saturated steam and the residual air in these pockets will eventually reach "sterilizing temperature" but resemble a microscopic hot air oven condition, requiring much higher temperatures and longer exposure times to achieve sterility of the product. If equilibration time at sterilization phase exceeds 15 seconds, sterilization conditions will not be achieved and the thermocouple will then measure hot air temperature. Superheated steam has a temperature exceeding the boiling point at a given air pressure and an energy conversion phase will not occur, the energy of the overheated steam will be spent in heating up the instruments and this will again be equivalent to dry heat sterilization conditions. Supersaturated or supermoist steam (to low temperature) will result in failure of steam to penetrate the items in the sterilizer. Therefore, the sterilization temperature must be held within a very limited temperature range and achieved within a relatively short period of time in order to meet sterilization conditions. Both types of thermocouples, as well as data loggers, showed that the time lag is significantly greater in location C, which is located in the plastic component of the handpiece, 45mm from the coupling. The thermocouples and data loggers used in these experiments are widely used in industry to validate steam sterilization processes. As a result only handpiece position C, identified during preliminary experiments as the position taking longest to come up to temperature, was replicated in both the non-vacuum downward/gravity displacement, type-N and vacuum type B process with fractionated pre-vacuum and post-vacuum sterilisation processes. One of the technical difficulties in determining sterilization of narrow lumened devices is whether temperatures achieved are due to conducted heat through the body of the medical device or the presence of saturated steam. An advantage of using dataloggers to confirm the findings of the thermocouples is that the sensing ends are insulated making it unlikely that recordings are significantly influenced by conducted heat. The use of data loggers to record critical

parameters is more efficient in terms of time, due to the fact that the use of thermocouples requires breaking the seals of sterilizers and sensing ends of thermocouples are more prone to breakage, which requires re-calibration. Measurements from inside the handpiece lumens showed a lag of up to 150 sec (failure to achieve sterilization temperature for 83% of the 3 minute holding time) demonstrating the potential for adverse events and by definition unsterile. Recordings taken at different locations in the handpieces and the BDT using the non-vacuum downward/gravity displacement, type-N sterilizing cycle were compared to a vacuum sterilization process, which showed time differences of -1 - 3 sec in the handpieces compared to the chamber in all tested locations. The time difference observed in the non-vacuum downward/gravity displacement, type-N sterilizing cycle indicates that residual air inside the handpieces is likely to be the reason for the delayed penetration of steam and resulting delay in achievement of sterilization conditions.

Within the UK there has been a long standing reluctance by some dental organisations (21) to recognise the technical limitations of the non-vacuum downward/gravity displacement, type-N sterilization process for dental handpieces, more recent technical guidance (22) appears to advocate vacuum or special cycles for handpieces, although there is little recent evidence to suggest a move away from the traditional use of the non-vacuum downward/gravity displacement, type-N sterilizer in the UK (12,13) and elsewhere (14). Guidance from the CDC (23) recommends handpieces are “always heat sterilized” without highlighting whether a vacuum or non-vacuum downward/gravity displacement, type-N process be used this study suggests that specification of the steam sterilization process should be considered.

The results from this study confirm that non-vacuum downward gravity displacement, type-N sterilizing processes are unreliable and insufficient for achieving sterilization conditions. Steam sterilization processes that effectively remove residual air, such as type B or type S processes, (15-19) should be recommended especially where lumened handpieces are used to deliver more invasive dental treatments such as dental implant placement, surgical extractions and endodontic procedures.

Disclosure

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Figure 1: Test locations within the handpiece

Figure 2: Example of the time difference between the chamber and the inside of the handpieces reaching sterilization temperature (134^{o}C)

Table I Summary of data (difference in seconds between sterilizer chamber and inside of handpiece reaching 134℃) from different locations within different handpiece channels using different thermometric measurements

Location in HP	TC type	Sterilization Process	No. of tests	No. achieving >15s	Median (s)	Range (s)	Mean (s)	SD (s)
A	**Regular**	**N**	**33**	5	5.0	2-33	8.0	7.9
Air channel	**Thin**	**N**	**9**	1	9.0	4-52	13.0	14.9
	Logger	**B**	**9**	0	2.0	0-3	1.8	1.0
B	**Regular**	**N**	**23**	3	2.0	0-23	5.0	6.3
Air channel	**Thin**	**N**	**9**	4	7.0	-2-34	13.7	12.9
	Logger	**B**	**9**	0	2.0	1-3	2.1	0.9
C	**Regular**	**N**	**12**	4	3.5	2-150	23.0	42.3
Air channel	**Thin**	**N**	**9**	5	23.0	5-27	18.7	10.4
	Logger	**N**	**9**	9	58.0	53-143	76.8	32.0
	Logger	**B**	**9**	0	0.0	-1-3	0.3	1.3
C Spray channel	**Thin**	**N**	**9**	5	25.0	4-78	28.6	26.6

HP: hand piece; TC: thermocouple; SD: standard deviation