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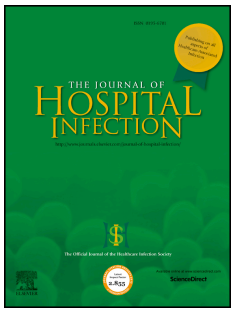

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Failure of non-vacuum steam sterilization processes for dental handpieces

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Running title: Failure of non-vacuum sterilizers for dental handpieces

Summary

Background: Dental handpieces are used in critical and semi-critical operative interventions. Although a number of dental professional bodies recommend that dental handpieces are sterilized between patient use there is a lack of clarity and understanding of the effectiveness of different steam sterilization processes. The internal mechanisms of dental handpieces contain narrow lumens (0·8-2·3mm) which can impedethe removal of air and ingress of saturated steam required to achieve sterilization conditions.

Aim: To identify the extent of sterilization failure in dental handpieces using a non-vacuum process.

Methods: *In-vitro* and *in-vivo* investigations were conducted on commonly used UK benchtop steam sterilizers and three different types of dental handpieces. The sterilization process was monitored inside the lumens of dental handpieces using thermometric (TM) methods (dataloggers), chemical indicators (CI) and biological indicators (BI).

Findings: All three methods of assessing achievement of sterility within dental handpieces that had been exposed to non-vacuum sterilization conditions demonstrated a significant number of failures (CI=8/3,024(fails/n tests); BI=15/3,024; TM=56/56) compared to vacuum sterilization conditions (CI=2/1,944; BI=0/1,944; TM=0/36). The dental handpiece most likely to fail sterilization in the non-vacuum process was the surgical handpiece. Non-vacuum sterilizers located in general dental practice had a higher rate of sterilization failure (CI=25/1,620; BI=32/1,620; TM=56/56) with no failures in vacuum process.

Conclusion: Non-vacuum downward/gravity displacement, type-N steam sterilizers are an unreliable method for sterilization of dental handpieces in general dental practice. The handpiece most likely to fail sterilization is the type most frequently used for surgical interventions.

Keywords: dental handpieces, steam sterilization, non-vacuum sterilizers, vacuum sterilizers, data loggers, biological indicators, chemical indicators, hollow instrument, sterility assurance.

Background

The dental turbine and motor are widely used Worldwide to undertake a variety of critical and semi-critical clinical interventions. Dental handpieces become contaminated externally and internally during patient treatment (1-3). The challenge to effectively sterilize dental handpieces lies in their construction with geared or turbine drive mechanisms and lumens (0.9-2.3mm diameter) carrying air and water that restrict access for cleaning and steam ingress for sterilization.

The European standard for benchtop (tabletop) steam sterilizers (4) describes three different processes by which these benchtop machines can remove air to allow direct access of saturated steam to the surfaces of surgical instruments. Type N, which is a non-vacuum and passive air displacement process, type B and S, which achieve air removal using fractionated pre/post-vacuum phases and special cycles, respectively. Manufacturers of both sterilizers and dental handpieces recommend that this equipment be sterilized using a vacuum process, (for example, instructions for handpiece sterilization (5) and benchtop steam sterilizers(6)). Non-vacuum sterilizers are still widely used Worldwide (7,8) and in the UK (9,10).

A number of professional organizations, for example the WHO (11), CDC (12), Australian standard/New Zealand standard (AS/NZS) (7), American National Standards Institute/Association for the Advancement of Medical Instrumentation (ANSI/AAMI) (8), UK Department of Health (DOH) (13) and British Dental Association (BDA) (17) recommend that dental handpieces are sterilized prior to re-use. However, there is a lack of specification by these organizations on the type of process used to achieve sterilization despite the International standard specifications[15,16]. We present a comprehensive series of laboratory and field investigations using biological indicators (BI), chemical indicators (CI) and thermometric (TM) measurements that demonstrate that the widely used Type N sterilization process is unreliable for dental handpieces and pose a risk of cross-infection.

Materials and methods

Dental handpieces

For each sterilization cycle investigated, a standard test load consisting of 3 different types of handpieces were used: dental air turbine (TA-98 C LED, W&H, Austria), straight surgical handpiece (S11, W&H, Austria), slow speed motor (WA-56 W&H, Austria) and a helix process challenge device (Albert Browne International Ltd, Leicester, UK) was used as a control (Supplemental Figure 1). For each load there were three replicates for each handpiece

(total n=9). Handpieces undergoing vacuum sterilization were placed in sealable sterilization pouches (Steris, UK) before sterilization. Test runs with handpieces were run with small loads (0·5kg) and full loads (4·5 kg) set up as per sterilizer manufacturers' instructions and comprised steel dental instruments, such as probes, mirrors and forceps. Experiments were performed in triplicate as a minimum.

Chemical indicators

Each type of handpiece was inoculated with CI compliant with International standards (17,18) (Albert Browne International Ltd, Leicester, UK). In order to accommodate the passage of the CI into the lumens of the handpieces these were cut to size. A previous series of validation experiments (data not shown) had demonstrated that this process did not affect the behavior of the CI. A sterilization cycle pass was determined by visualization of the CI colour change as recommended by the manufacturer. A Helix process challenge device (Albert Browne International Ltd, Leicester, UK) were used as a control for steam penetration. For each sterilization cycle CI monitoring was undertaken in 3 different handpieces.

Biological indicators

BI strips (mini spore strips, Excelsior Scientific, Cambridgeshire, UK) comprising 10^6 spores of *Geobacillus stearothermophilus* with a D_{121} of 1·8 – 2·5 min (19,20) were inserted into handpieces at similar locations to the CI (see Tables I & II). For each sterilization cycle BI monitoring was undertaken in 3 different handpieces. Positive controls were placed on the loading tray in the sterilizer chamber. Growth controls comprised unexposed BI strips placed in tryptic soy broth (TSB) for each sterilizer batch run.

Thermometric measurement

Temperature recording using data loggers (Ellab, Hillerød, Denmark) inside the handpieces was only possible in the dental turbine air drive channel (diameter 2·3mm, length 80mm, volume 332ml) due to accessibility of the data logger temperature probe (dimensions 2·0 mm). The tip of the thermocouple probe was placed 45mm from the coupling end of the turbine, two air turbine handpieces were monitored per load (Supplemental Figure 1). Previous validation work (21) had determined the optimum position for measurement. Ellab's ValSuit Basic software was used for analysing the recorded data. Reports were saved as pdf files. Thermometric failures were classified pass/fail in one of three ways; the time delay between the temperature recorded in the chamber and the load should not exceed 3 seconds

(22), time delay should not exceed 15 seconds (4) and a temperature lag of no more than 2°C from the point where the chamber reaches 134°C compared to the load (23).

In-vitro experiments on bench-top sterilizers

For this series of experiments we investigated three different makes of non-vacuum downward/gravity displacement, type-N cycle sterilizers that included two different models of an Alpha (Prestige Medical, Blackburn, UK), and Little Sister 3 (Eschmann, Eschmann House, Lancing, West Sussex, UK) and compared to a vacuum (type B cycle) sterilizer (two different models of a Lisa, W&H). Each sterilizer had been validated and tested before use by the suppliers. For each sterilizer a Bowie-Dick test (BDT) was used as a control. Small load and full load cycles (as per manufacturer's instructions) were compared and experiments were performed in triplicate. These makes and models are commonly found in UK dental practices (9).

General dental practice investigations

Local dental practices were invited to participate in an investigation of the performance of their steam sterilizers. Dental practices in Scotland are subject to a dental practice inspection by a local dental advisor, this visit incorporates a review of the documentation linked to the periodic testing and annual revalidation of the practice benchtop steam sterilizer. All practices visited had successfully passed their dental practice inspection although we did not review the documentation associated with the benchtop steam sterilizers in this investigation. For each dental practice we visited, the same standard load as that used in the laboratory investigation (Supplemental Figure 1) was used. Both non-vacuum downward/gravity displacement, type-N and vacuum (type B) sterilization cycles were tested and three cycles were performed in each sterilizer.

Results

In-vitro testing

Three non-vacuum Alpha (Prestige) sterilizers were tested. The overall cycle time was 35 minutes with a plateau time of 3·5 min at 134°C. The time difference between handpieces and chamber reaching the optimum (range = 25 – 40 sec) resulted in thermometric fails. Three non-vacuum Little Sister 3 (Eschmann) were tested (see Supplemental Figure 2 for typical temperature/time cycle profile). The overall cycle time was 17 - 20 minutes with a plateau time of 3·5 - 6·5 min at 134°C. A full load of 5 kg (as per manufacturer's instructions) was not tested because the sterilizers failed the cycle with full loads.

Summaries of CI and BI test results are shown in Table I. The handpiece mostly likely to fail CI tests (n=4/504) was the surgical handpiece and in the coupling location (where the handpiece connects to the air drive supply). The handpiece most likely to fail BI tests (n= 12/504) was the surgical handpiece in the chuck lever position (Table I).

The results for CI, BI and TM tests on vacuum sterilizers (Lisa W&H, Austria) are summarized in Table I. Pressure recordings from the sterilizer chamber demonstrated three vacuum pulses at 0.2 bar and the overall cycle time was 30 – 45 minutes with a plateau time of 4 min and 10 sec at 134°C (see Supplemental Figure 3 for typical time/temperature cycle). No BI fails (1,944 tests) and 2 CI fails (1,944 tests) were detected. The time difference in achieving 134°C between the inner of the handpiece and sterilizer chamber ranged from 0 – 3 sec and as a result all handpiece tests (n= 36) constituted thermometric passes. All control Helix PCD tests achieved pass conditions.

Investigations in general dental practice

Five non-vacuum benchtop sterilizers in use at general dental practices were tested and results summarized in Table II. Sterilization cycle times ranged from 16 – 25 min, with plateau periods of 3·5 – 4·5 min at 134˚C. The period over which temperature differences between the sterilizer chamber and the inside of the handpieces occurred ranged from 0 sec – N/A, which meant that some handpieces did not achieve sterilization temperature during the whole cycle (see Supplemental Figure 4 for time/temperature cycle). Compared to the *in-vitro* study, higher failure rates were detected for both CI's (n=25/1,620) and BI's (n=32/1,620). In contrast to the in-vitro study all handpiece types demonstrated either a CI or BI fail (or combination of both). In both studies the surgical handpiece and the chuck lever location was the type and location most likely to fail sterilization. Thermometric monitoring within the air channel of the air turbine revealed that all handpiece tests (n=30) failed to achieve temperature equilibration between the chamber and lumen of handpiece within 15 seconds. The results for CI, BI and thermometric tests on vacuum sterilizers situated in general dental practice are summarized in Table II. No BI fails (162 tests), CI fails (162 tests) or thermometric fails (n=18) were detected. All control helix PCD tests achieved pass conditions.

Discussion

The use of only temperature and pressure measurements in order to investigate the presence of saturated steam inside lumens has been challenged by some workers using novel

investigative techniques (24). In order to address these potential criticisms, we also included the use of CI and BI within handpieces to assess steam penetration. Chemical indicators for sterilization processes typically comprise colour change printed chemistry designed to react to single or multiple parameters during sterilization cycles (18). Class 5 integrating indicators used in this series of experiments are designed to react to several critical variables (in this case time, temperature and moist heat) and are considered equivalent to or exceed the performance requirements of ISO 11138 for BI's (19,20). We report CI failure rates of 31/4,644 inside dental handpieces in the non-vacuum process. The detection of two CI failures in the turbine position of high speed handpieces in the vacuum cycle is difficult to explain (n=2/2,106) as all other measurements (thermometric and BI) all achieved pass conditions, all controls responded as expected and repeat tests have failed to replicate this result.

BI's for moist-heat sterilization use the 'worst case' microbe *Geobacillus stearothermophilus* endospores (19,20). Due to a number of imprecisions in determining and calculating small numbers of bacterial numbers surviving sterilization processes the concept of sterility assurance is used in the production of sterile products which gives a numerical value to the probability of a single surviving organism remaining to contaminate a processed product. For medical devices to be labelled "sterile" they are deemed to have less than one chance in a million of a single, finished product item containing a viable organism (15,16). In this study we discovered relatively large numbers of BI sterilization failures (47 failures from 4,464 tests) in the non-vacuum process, with no failures in the vacuum process. The survival of bacterial endospores in this study following exposure (heat-up, plateau and cool down) time periods of 35 minutes and for some makes of non-vacuum steam sterilizer plateau periods of 134°C for up to 6.5 minutes demonstrates gross failure of achievement of sterilization conditions within the inner locations of the handpieces. Previous reports on the ability of *G. stearothermophilus* spores placed in handpieces to survive steam sterilization has been reported by some (25) but not all authors (26). The variation in results probably due to differences in equipment tested, BI bioburden, presentation and recovery.

Estimating the risk of harm from handpiece sterilization failures in the context of an estimated millions of dental treatment episodes annually is challenging, especially in the absence of systematic data collating post-operative infection incidents. Most risk assessment and look back exercises in dental treatment are linked to possible patient to patient and dentist to patient transmission of blood borne viruses (27). Whether known and reported

transmission events of hepatitis B and C are linked to the failure of non-vacuum sterilizers and handpieces is often impossible to determine long after a transmission event has occurred (28, 29). Furthermore, viruses especially BBV's are extremely thermolabile and the probability of survival even in the non-vacuum process is remote. However, there remains the possibility that classic bacterial pathogens such as, *S. aureus* could survive handpiece sterilization failures. Circumstantial evidence linked to recovery of *S. aureus* from used handpieces (3) and dental infections such as implant infections already exists (30,31). Other examples include recovery of *Propionibacterium acnes* and *Staphylococcus epidermidis* from used handpieces (3) and other authors demonstrating the role of these microbes in recurrent endodontic infections (32). Clearly, recovery and typing of an isolate from a contaminated handpiece and wound infection would help provide conclusive evidence. The observation that higher sterilization failure rates occur in surgical handpieces suggests that the focus for risk reduction measures should be on recommendations linked to surgical interventions and the effective decontamination and use of active air removal steam sterilization processes that have been validated by both handpiece and sterilizer manufacturers.

In conclusion, we report investigation of sterilization process outcome using a unique combination of TM, CI and BI tests according to International standards. These test results demonstrate that the non-vacuum process is unreliable and fails to achieve sterilization within dental handpieces, especially surgical handpieces that are commonly used in more invasive dental procedures such as dental implants.

Disclosure

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W&H and Ellab had no role in the design of experiments, recording of results, interpretation of data and conclusions.

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Table I Summary of *in-vitro* BI, CI and thermometric measurements inside dental handpieces processed inside non-vacuum (Type N) and vacuum (Type B) sterilisers. The results for Type N processes comprise testing of six different sterilizers from two different manufacturers (three of each model) and a minimum of three cycles for each machine. The results for Type B processes comprise testing of three different sterilizers (two models) from one manufacturer and a minimum of three cycles for each machine.

	BI test (fails/tests)		CI test (fails/tests)		Thermometric test (Fail criteria: chamber vs handpiece >3 sec)		Thermometric fails (Fail criteria: chamber vs handpiece >15 sec)		Thermometric fails (Fail criteria: chamber vs handpiece >2°C)	
Handpiece Type & position of indicator	**Type N**	**Type B**	**Type N**	**Type B**	**Type N**	**Type B**	**Type N**	**Type B**	**Type N**	**Type B**
Turbine/ head	0/504	0/324	0/504	2/324	-	-	-	-	-	-
Turbine/ Mid Air channel	0/504	0/324	1/504	0/324	56/56	0/36	56/56	0/36	42/56	0/36
Turbine/ Distal spray channel (CI) Distal air channel (BI)	1/504	0/324	1/504	0/324	-	-	-	-	-	-
Surgical/ chuck lever	8/504	0/324	1/504	0/324	-	-	-	-	-	-
Surgical/ coupling	4/504	0/324	4/504	0/324	-	-	-	-	-	-
Air motor/ inside	2/504	0/324	1/504	0/324	-	-	-	-	-	-
Total	**15/3,024**	**0/1,944**	**8/3,024**	**2/1,944**	**56/56**	**0/36**	**56/56**	**0/36**	**42/56**	**0/36**

Table II Summary of sterilizer testing from general dental practices BI, CI and thermometric measurements inside dental handpieces. For non-vacuum sterilizers (Type N) the results comprise testing of five sterilizers (three different models from one manufacturer). For vacuum sterilisers (Type B) the results comprise testing of three sterilizers comprising one model from two manufacturers.

	BI test (fails/tests)		**CI test (fails/tests)**		**Thermometric test (Fail criteria: chamber vs handpiece >3 sec)**		**Thermometric fails (Fail criteria: chamber vs handpiece >15 sec)**		**Thermometric fails (Fail criteria: chamber vs handpiece >2°C)**	
Handpiece Type & position of indicator	Type N	Type B	Type N	Type B	Type N	Type B	Type N	Type B	Type N	Type B
Turbine/ head	0/270	0/27	1/270	0/27	-	-	-	-	-	-
Turbine/ Mid Air channel	0/270	0/27	0/270	0/27	30/30	0/18	30/30	0/18	28/30	0/18
Turbine/ Distal spray channel (CI) Distal air channel (BI)	6/270	0/27	0/270	0/27	-	-	-	-	-	-
Surgical/ chuck lever	22/270	0/27	9/270	0/27	-	-	-	-	-	-
Surgical/ coupling	3/270	0/27	5/270	0/27	-	-	-	-	-	-
Air motor/ inside	7/270	0/27	4/270	0/27	-	-	-	-	-	-
Total	**32/1,620**	**0/162**	**25/1,620**	**0/162**	**30/30**	**0/18**	**30/30**	**0/18**	**28/30**	**0/18**