Autoclave performance in private dental practices in Hong Kong

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ABSTRACT Objectives. In dental offices, sterilization of instruments is one of the most important aspects of infection control. Autoclave effectiveness in killing microorganisms can be verified by spore tests. The purpose of this study was to investigate the sterilization procedures of private dental offices in Hong Kong, and to test the effectiveness of their autoclaves using biological indicators. Methods. Packages of an 18-item questionnaire and two biological indicators were sent to 402 private dental practices in Hong Kong. They were instructed to complete the questionnaire, and perform a spore test in their autoclave using the biological indicators and return them for incubation. Results. One hundred and eighty-two practices responded, with a response rate of 45%. Excluding three incomplete questionnaires and four practices using dry heat oven, a total of 175 autoclaves were tested. Thirteen (7%) of the autoclaves failed the initial spore test. Twelve of these practices performed a re-test, whereupon two (1%) of the autoclaves failed again. Among these 175 autoclaves, 77 (44%) were the Fuji Elite model. The commonest (n=72; 41%) packing material and method entailed sterilization pouches. Twenty-three (13%) of the respondents used improper sterilization time/temperature conditions for processing the instruments. For autoclaves older than 1 year, only 38% (n=58) had been serviced in the last year. One hundred and nine (62%) of the respondents used chemical indicators and only seven (4%) used biological indicators to monitor sterilization. Conclusion. Autoclaves in private dental practice in Hong Kong should be regularly checked, and their effectiveness routinely monitored. The use of biological indicators to monitor the sterilization was uncommon and knowledge about proper autoclaves usage needs improving.

Key words: Infection control; Sterilization

Introduction

Infection control has been a prime concern in clinical dentistry. The most important aspect of infection control programs is the proper reprocessing of contaminated instruments so that cross infection is prevented. The Centers for Disease Control and Prevention (CDC) of the US and other authorities recommend that all instruments and other devices used intraorally should be sterilized after use. Currently, four main types of sterilization are used in dental offices, namely steam autoclaves, dry heat ovens, unsaturated chemical vapor, and ethylene oxide gas sterilizers. Among these, steam sterilization is the most widely used for wrapped and unwrapped critical and semi-critical items that are not sensitive to heat and moisture. In order to kill the microorganisms, steam sterilization requires the instruments having direct contact with steam at a specified temperature and pressure for a specified time. There are two basic types of steam sterilizers: (i) gravity displacement (non-vacuum) and (ii) vacuum-assisted autoclaves. The gravity displacement (non-vacuum) autoclaves sterilize instruments with saturated steam, emanating from an external generator or self-generated and admitted to the sterilizing chamber through special lines. Unsaturated air is expelled from the chamber through a vent. The problem with using saturated steam is the possible trapping of expelled air. This air pocket may render the sterilization ineffective because steam cannot make contact with the instrument surface. This type of sterilizer is therefore mainly suitable for solid, unwrapped instruments, but is unsuitable for instruments in pouches, porous or wrapped loads, and...
more especially for instruments with hollow or narrow lumens. On the other hand, ‘pre-vacuum autoclaves’ are fitted with an electric pump to create a vacuum in the chamber to ensure complete air removal before the chamber is pressurized with steam. This enables the steam to circulate freely around the instruments. Compared to gravity displacement, this procedure allows faster and more positive steam penetration throughout the entire load, and can be effectively attained for all types of loads, including solid, hollow, porous, pouch, and wrapped items. According to the current European Standard EN13060: 2004, sterilization cycles of small steam sterilizers suitable for dental offices are classified according to the types of load they are intended to process under three categories, namely, B, N, and S. Autoclave with B cycles has a vacuum pump to remove air from the chamber, which is suitable for all wrapped, solid, hollow, and porous loads. Type N cycles are based on gravity displacement and are intended for non-wrapped solid loads. Type S cycles are intended for loads specified by the manufacturer of the sterilizer.

**Sterilization monitoring**

A completed sterilization cycle does not guarantee that a load has been processed properly, or that the instruments are truly sterilized. Steam sterilization or autoclaving may not be 100% effective at killing all microorganisms under all circumstances. There are a number of reasons why sterilization by autoclaving may fail 5, namely:

1. Inappropriate packaging of material (e.g. using closed/solid containers in a steam sterilizer);
2. Overloading of instruments, which prevents adequate exposure of all instruments to the pressurized steam;
3. Improper equipment maintenance;
4. Improper cycle time and conditions; and
5. Leakage of the sterilizer.

A proper sterilization monitoring process, routinely using some forms of physicochemical and biological indicators (BIs), can detect most of the above problems. Parameters have been developed to evaluate both sterilizing conditions and procedure effectiveness. For instance, the operator can record the cycle time, temperature, and pressure of the autoclave of each load. This is very useful for documentation/monitoring of quality control, but does not verify sterilization. Chemical indicators designed solely to indicate whether a load has been processed or not are called process indicators. They are usually heat-sensitive chemicals that display a color or physical change at a specific temperature over time. Chemical indicators are manufactured in several forms, including pads, cards, strips, vials, and commonly as tapes. Indicators printed on autoclave tapes and on sterilization pouches are examples.

Other chemical indicators may include multi-parameter indicators, integrating indicators, or emulating indicators. The chemical formulations of these indicators are sensitive to the correct combination of the three factors necessary for sterilization: time, temperature, and saturated steam. To ensure heat penetration to all instruments during each cycle, CDC 1 and American Dental Association 2 recommend that a chemical indicator should be placed inside and in the center of a load of unwrapped instruments. Although process indicators can be conveniently used to differentiate between processed and unprocessed loads by providing an immediate, visual indication of sterilizing conditions, they do not verify sterility. Therefore, they are not replacements for biological monitoring. Even when sterilizer gauges display correct values for internal conditions and chemical indicators show that appropriate chamber conditions have been reached to achieve sterilization, they do not, however, guarantee that sterilization has occurred.

**Biological monitoring**

Biological monitoring is the only means of verifying sterilization; employment of calibrated BIs remains the main guarantee of sterilization 5. Biological indicators work by introducing live, highly resistant, nonpathogenic spores into a sterilization cycle. Spores of bacteria *Bacillus stearothermophilus* (for steam and chemical vapor sterilizers) and *Bacillus subtilis* (for dry heat sterilizers) are commonly used, because they are highly resistant to heat, more so than most viral, bacterial, and fungal pathogens. After processing in a sterilization cycle, the spores are placed in a culture medium and incubated at the respective optimum temperature. If the sterilization process kills all the spores, no growth will occur. If there are surviving spores, growth can occur and this is usually indicated by a color change of the culture medium. Bacterial spores are far more resistant to heat than vegetative bacteria or viruses (including human immunodeficiency virus [HIV], hepatitis B virus [HBV], and coronavirus). They are also present in greater numbers than common microbial contaminants found on patient-care equipment. If these spores are inactivated after a sterilization cycle, no other organisms should survive and the load is assumed to be sterile 6. Dry spores are available in two forms. Conventional spore strips are packaged in sealed envelopes. They may become contaminated on being transferred to the growth medium for incubation (after
the sterilization cycle). The second type of dry spore strip is incorporated in a self-contained vial, which contains both the spores and the growth medium (Figure 1). This design eliminates the possibility of contamination. Commercial BIs are produced according to given specifications, e.g. number of spores per spore strip and heat resistance (decimal reduction value: exposure time required to secure inactivation of 90% of a population of test organisms under stated condition).

Biological monitoring can be performed in two ways. For in-office incubators, spore vials usually give results within 24 to 48 hours (Figure 2). Mail-in spore monitoring services usually take a week. Although it takes longer to get results using a mail-in service, third-party programs may offer more credibility than in-house monitoring. Besides, a delay of 7 days in processing of BIs has no important effect on the results. Only in-office biological monitoring is available in Hong Kong, whereas mail-in sterilization services (e.g. from private companies or dental schools) are common in the US.

In 1997, a study showed that the most common type of sterilizer used by general dental practitioners in Hong Kong was the steam autoclave and over 90% of practices did not perform spore tests to monitor the effectiveness of their machines. Studies in other countries have used BIs to monitor the effectiveness of instrument sterilizers in dental practices. Thus, studies in the United Kingdom, Ireland, the US, and Denmark reported spore test failure rates of 2%, 11.3%, 6%, and 7.3%, respectively. A retrospective study of a sterilization monitoring service showed that there was an overall 2.8% sterilization failure rate of autoclaves in 58 268 spore tests over a period of 16 years. It is therefore evident that a significant number of dental office autoclaves are not effective in killing all microorganisms during a sterilization cycle. Conceivably, faulty sterilization procedures may cause transmission of a number of infectious agents, such as HBV and HIV in dental offices. The CDC and other authorities therefore recommend that biological monitoring should be regularly performed to verify the sterilization performance of each sterilizer. In the US, several states have laws requiring regular spore testing of dental practice autoclaves. In Hong Kong, there is no such regulation regarding biological monitoring of sterilizers, so information on the performance of autoclaves in private dental offices is lacking.

The purpose of this study was to investigate the sterilization procedures of private dental offices in Hong Kong, and to test the effectiveness of their autoclaves using BIs.

Materials and methods

This study was targeted at private dental practitioners in Hong Kong. Dentists working in government dental services, hospitals, and universities were excluded. The names and addresses of 414 private dental practitioners were randomly drawn from a list of 1679 dentists registered with the Dental Council of Hong Kong. In 2004, packets of study materials were mailed to the primary office addresses of the selected practitioners. Each packet contained:

1. An introductory letter describing the nature of the research project and an invitation to participate; practitioners were assured of the confidentiality of all results;
2. A self-administered questionnaire (Appendix) to elicit information regarding demographic information,
sterilization methods, and the use of BIs to monitor sterilization performance;

3. Two BIs (Attest™ 1262, Lot No. 2004-12AA/B, 3M Healthcare, St. Paul, US), one was used for testing and the other one as a control, and details about their function and instructions were enclosed; and

4. A return stamped envelope with assigned identification number.

Reminders were sent to all non-respondents 2 weeks after the first mailing to encourage response. The practitioners were instructed to process one of the BIs in their autoclaves in the first routine sterilization cycle of the first working day of a week. Specific instructions were given to operate the autoclave in the manner normally used by the office. The BIs should be placed in the same type of sterilizing bags, pouches, package, kits, containers etc. in the center of a normal load. For offices that sterilize all instruments unwrapped, the BI was to be placed in the center of a normal load. Dentists were requested to provide information about operating conditions for the tested autoclave cycle (i.e. temperature, holding time, and packaging method). The processed BI, unprocessed control BI, and the questionnaire were to be returned using the reply envelope.

Upon receipt, the returned BIs were checked for integrity and the presence of color change of the chemical indicators on the outside. They were then incubated for 48 hours at 56°C in Attest™ biological incubators (3M Healthcare, St. Paul, USA) [Figure 2] immediately to determine the presence of viable spores, according to the manufacturer’s instructions. The color change of the culture medium was recorded and verified by another examiner. Dentists whose BI cultures were negative (indicating adequate sterilization) and positive (indicating no lethal damage to spores as a result of mail transit, storage or handling) received a corresponding report on the test result. If the control BI culture was negative (indicating lethal damage to spores as a result of mail transit, storage or handling), another set of BIs were sent to those dentists for repeated spore testing. Dental practices whose autoclaves produced positive BI results (indicating inadequate sterilization) were contacted by phone and mail; and advice on how to improve the sterilization performance was given. In addition, new BIs for repeated spore tests were sent. If the repeated spore test result was again positive, the parties were immediately contacted and advised not to use that autoclave.

Though this study did not go through ethics committee approval in the local community, strict confidentiality was assured throughout the research process.

The responses to the questionnaire and results of the spore tests were entered into a spreadsheet (Excel 97, Microsoft Corporation, Redmond [WA], USA) and descriptive statistics were performed. The number and percentage of positive spore tests were tabulated and analyzed.

**Results**

Four hundred and fourteen mails were sent out; 12 were returned because of incorrect addresses, resulting in a valid sample of 402. A total of 182 private dental practices responded to this survey, giving a response rate of 45%.

Three questionnaires were incompletely answered, and were excluded from this study, resulting in 179 valid responses for analysis. One BI ampule was found to be damaged and a new ampule was re-sent. One returned BI ampule was found to have melted and the corresponding respondent was also requested to repeat the spore test. Only one control BI cultured negative, indicating that spores might have been killed during delivery. The dentist who returned this negative control was requested to repeat the spore test. Four (2%) respondents were using dry heat oven and so were not required to perform the spore test and did not qualify for the study. Therefore 179 completed questionnaires and 175 spore tests were assessed in this study.

**Demographic data**

Among the 179 respondents, years since graduation ranged from 1 to 46 with a mean of 16 (Table 1), and 105 (59%) dentists had graduated from the University of Hong Kong, a local dental school founded in 1980. One hundred
and twenty-two (68%) dentists were in solo practice, 30 (17%) were partners, and 17 (10%) were associates in group practices. Others included eight non-government organizations, one Health Maintenance Organization, and one charitable clinic. The majority (n=164; 92%) of the respondents practiced general dentistry, six practiced orthodontics, four periodontics, two endodontics, two prosthodontics, and one maxillofacial surgery.

Fifty (28%) respondents reported that they had attended continuing education courses on infection control in the last year, and 46 (26%) claimed their dental surgery assistants (DSAs) received formal training in the use of sterilizers. The majority (n=153; 86%) agreed that routine biological monitoring of sterilizers was necessary, though only seven (4%) used BIs for regular monitoring of their sterilizations.

One hundred and twenty-one (68%) respondents used gravity displacement steam autoclaves in their dental offices, whilst 41 (23%) respondents used vacuum-assisted types. Four (2%) respondents used dry heat ovens, but none reported using unsaturated chemical vapor sterilizers. Six (3%) reported that they were not sure what type of the sterilizer they were using. Seven claimed they were using other types of sterilizers, but answers to the questionnaire indicated they were using gravity displacement autoclaves.

Among the 179 respondents, 175 had performed the spore test. The types of autoclaves used in the spore test are listed in Table 2. The commonest (n=77; 44%) type was the Fuji Elite (Fuji Medical Instrument Co. Ltd., Tokyo, Japan), followed by the Midmark (Midmark Corporation Medical Equipment, Ohio, US) [n=35; 20%]. For the vacuum-assisted type, eight were using LISA MB17 (W & H, Burmoos, Austria).

The commonest (n=72; 41%) packaging material and method entailed sterilization pouches. Forty-four (25%) practices used perforated trays, while the other 47 (27%) did not use any packaging material. Three (2%) reported that they used a non-perforated tray (Table 3). Reported sterilization duration and temperature conditions varied (Table 4). Sterilization temperature ranged from 120 to 150°C and sterilization duration from 3 to 45 minutes. The most common (n=73; 42%) sterilization duration used were 11 to 20 minutes, and the majority (n=110; 63%) used sterilization temperatures of 131 to 135°C.

The mean (range, 1 month-24 years) period of service

| Table 2 Autoclaves used by the respondents | No. (%) of respondents |
| Manufacturer and model | |
| Fuji Medical Instrument, Fuji Elite EAC-2200 | 57 (33) |
| Fuji Medical Instrument, Fuji Elite other models | 20 (11) |
| Midmark Corporation Medical Equipment, Midmark M7 | 30 (17) |
| Midmark Corporation Medical Equipment, Midmark M9 and other models | 5 (3) |
| W & H, LISA MB17 Class B Vacuum autoclaves | 8 (5) |
| Others | 55 (31) |
| Total | 175 |

| Table 3 Packaging and wrapping methods | No. (%) of respondents |
| Packaging material and method | |
| A pouch | 72 (41) |
| None/unwrapped | 47 (27) |
| A perforated tray | 44 (25) |
| A perforated tray with wrapping paper | 9 (5) |
| A non-perforated tray | 3 (2) |
| A container with filter system | 0 |
| Total | 175 |

| Table 4 Sterilization duration and temperature conditions | No. (%) of respondents (n=175) |
| Sterilization duration (minutes) | 1-10 | 60 (34) |
| | 11-20 | 73 (42) |
| | 21-30 | 23 (13) |
| | 40-45 | 7 (4) |
| | Others | 12 (7) |
| Sterilization temperature (°C) | 120-125 | 33 (19) |
| | 126-130 | 15 (9) |
| | 131-135 | 110 (63) |
| | 136-150 | 6 (3) |
| | Others | 11 (6) |
of the tested autoclaves was 5.6 years (Table 5). Twenty-one (12%) of the autoclaves had been used for less than 1 year, 49 (28%) were between 1 and 3 years, 41 (23%) were over 3 years but less than 6 years, and 55 (31%) were older than 6 years. Nine (5%) respondents reported that they did not know how old their autoclaves were. For those autoclaves (n=154) that were older than 1 year, 58 (38%) of them had been serviced within the past year of this survey. Regarding sterilization monitoring, 109 (62%) used chemical indicators, seven (4%) used BIs, and the remaining 59 (34%) did not answer this question. For those using chemical indicators, 57 (52%) used it on every load, nine (8%) every day, 10 (9%) every week, and 33 (30%) used them more than weekly. For those using BIs, two used them every week, two every month, one biweekly, and two occasionally. The mean number of sterilization cycles operated in a working day was 2.7.

### Spore tests results

Of the 175 pairs of BIs available for analysis (Table 6), 13 (7%) autoclaves failed to sterilize the spores in the first test. Of these, two autoclaves even failed to turn the chemical indicator band on the BIs from rose to brown. When the profile of these 13 practices was scrutinized, the following details were noted:

1. Eight dentists graduated from the University of Hong Kong, three from UK, one from the Philippines, and one from Singapore. The average years of practice since graduation was 15.5 years.
2. Six dentists were self-employed in solo practices and seven were in group practices. Twelve were general dental practitioners, and the others worked in a periodontal clinic.
3. Eight had not attended a continuing medical education (CME) course on infection control in the last year.
4. The DSAs from nine practices did not receive formal training in the use and maintenance of sterilizers.
5. All the failed autoclaves were gravity displacement steam autoclaves from two manufacturers, Fuji Elite and the Midmark. Of these, five were Fuji Elite model EAC-2200, four were Fuji Elite model EAC-1500, three were Midmark M7, and the last was Midmark M9. The failed autoclaves were, on average, 6.3 years old.
6. Nine practices used pouched instruments, but four (31%) used a time/temperature relationship below recommended standards.
7. Five practices did not use chemical indicators and 12 did not use BIs for sterilization monitoring.
8. Ten autoclaves had had no maintenance service within 1 year.

These 13 practices were offered a repeated test with proper instructions, such as avoidance of excessive packaging and overloading, and the use of proper times and temperatures for the sterilization cycle. The same packaging method that produced the failure was to be used again in the repeated test. One practice did not respond to the repeated spore test. Among 12 of these practices, two autoclaves failed to sterilize the spores in the repeated test and failed to affect the chemical indicator band on the label. Therefore, two (1%) out of 175 autoclaves were deemed to have failed on two occasions (Table 6).

### Discussion

#### Sampling

This was the first study to investigate autoclave performance in private dental practices in Hong Kong. It provides an indication of the depth of knowledge on the proper use of autoclaves, though it must be stressed that proper use of autoclaves is only one component
of infection control to prevent cross infection in a
dental surgery. The questionnaire response rate of 45% 
is similar to that of other studies in the UK (48%) 10 
and Ireland (40%) 11, which were considered satisfactory 
because of their complexity. Compliance may also have 
been affected by the unknown implications of a negative 
result.

Training and education

In all, 72% of the respondents reported not having 
attended any CME course on infection control in the 
last year and that only 26% of their DSAs had received 
formal training in the use of sterilizers. The low level 
of CME participation in infection control reflects on 
lack of popularity in Hong Kong and the fact that 
attendance is not mandatory for renewal of annual 
practicing licenses. The alarmingly low level of formal 
training of the DSAs in the use of sterilizers contrasts 
with levels exceeding 49% in the UK 10 and 75% in 
Ireland 11. Dental surgery assistants working in the 
Hong Kong private sector do not require formal training 
and most are uncertificated. In dental clinics, infection 
control techniques may be acquired only by informal 
training in individual practices. A study on UK dental 
nurses showed that uncertificated assistants performed 
more poorly in terms of knowledge on autoclave use 
21. Furthermore, in our study, respondents’ knowledge 
about the use of autoclaves appeared inadequate, as 
follows:

1. Six (3%) replied that they did not know what type of 
stereizer they were using.
2. Forty-one (23%) reported using vacuum-assisted 
steam autoclaves, however over 50% of them actually 
performed the spore test in gravity displacement 
autoclaves.
3. Three used a non-perforated tray to carry the 
instruments, which may prevent steam penetration in 
the sterilization cycle.
4. In all, 27 (38%) of 72 who pouched instruments 
claimed not to use chemical indicators, which under 
normal circumstances are present on a sterilization 
pouch, indicating that they were unaware of their 
presence and did not monitor any changes.
5. Twenty-three (13%) used inappropriate durations 
and temperature combinations for their sterilization 
process, which may be a major reason for 
ineffectiveness.

Thus, a need to improve the knowledge of proper 
sterilization procedures among dentists and DSAs in 
Hong Kong appears necessary.

Type of sterilizers

Almost all (98%) of the respondents reported using 
autoclaves in their practices, as reported in previous 
studies in Hong Kong 9, UK 10, and Ireland 11. By 
contrast, a study in the US 15 found that 47.5% of the 
sterilization devices used were chemical vapor sterilizers, 
43% were autoclaves, 9% were dry heat ovens, and 0.5% 
were ethylene oxide sterilizers. The difference may be 
due to differences in familiarity with certain types of 
sterilizers during training and early career experiences. 
Dry heat ovens require a longer time, usually more than 
1 hour, to complete a sterilization cycle 22, which may not 
be acceptable in the practicing environment of Hong 
Kong. Unsaturated chemical vapor sterilizers involve 
heating a chemical solution (primarily of alcohol with 
0.23% formaldehyde) in a closed, pressurized chamber. 
Such sterilizing solution and equipment were not readily 
available in Hong Kong, which may explain the local 
preference for other types of sterilizers. Accordingly, future 
studies on sterilizers in Hong Kong should concentrate 
on autoclaves. Interestingly, 64% of the respondents used 
autoclaves from two main manufacturers; their costs and 
peer influence may be the reasons. No previous study has 
compared the performance of autoclaves from different 
manufacturers.

Benchtop autoclaves can be divided into gravity 
displacement and vacuum-assisted types. In contrast to 
a study in UK, 23 which showed that only 3% of 217 
dental practices surveyed had a vacuum autoclave, about 
a quarter (23%) of our respondents claimed they were 
using models involving vacuum-assisted steam. Detailed 
analysis of the manufacturer and model number of the 
tested autoclaves revealed that at least 50% of the practices 
reporting such use were actually performing the spore test 
in a gravity displacement autoclave. Unlike requirements 
for radiographic equipment, there are no regulations to 
register the process and operation of autoclaves in Hong 
Kong.

Packaging materials and methods

Packaging materials (using pouches or wrapping 
paper) allow penetration of the sterilization agent and 
maintain sterility of the processed items thereafter, by 
avoiding recontamination in storage. Packaging materials 
should be matched for the type of sterilization process 
(e.g. duration/temperature relationship) being used 1.
Autoclave-pressurized steam has to penetrate through the packaging material and come into direct contact with instrument surfaces for effective sterilization. Improper packaging (e.g., using solid/closed containers/over wrapping) can impede the penetration of the steam. In our study, 46% of 175 practices either wrapped or pouchled instruments for sterilization, and 52% did not wrap instruments or use a perforated tray. Because of the difficulties of ensuring removal of air and penetration of steam into wrapped or pouchled instrument packs, in the UK, use of gravity displacement autoclaves are advocated to sterilize unwrapped solid instruments only. Thus, only 24.9% of 401 UK dental practices wrapped instruments during autoclaving. By contrast, US authorities discourage the sterilization of unwrapped instruments (flash sterilization), because this permits exposure to dust, airborne organisms, and other unnecessary contaminants before instrument use, unless they are to be deployed immediately or within a short period of time. In Hong Kong, packaging methods used by the private practices may be more variable, as there are no comparable local guidelines.

Three respondents used non-perforated trays for their sterilization cycle, though using such solid containers in an autoclave can impede the penetration of the steam and cause sterilization failure. Such usage warrants serious attention, even though the corresponding autoclaving passed the spore tests, as the risk of ineffective sterilization is nevertheless high.

**Sterilization time and temperature**

Direct exposure to saturated steam at 121°C for 15 minutes normally destroys all forms of microbial life, although, in practice additional time must be allowed for the temperature to reach this point at the center of packaged instruments. Thus, proper sterilization durations and temperatures (compatible with the type of packaging materials and loads) should be used. Our findings showed that many sterilization durations and temperature combinations ranged from 3 to 45 minutes and 120 to 150°C. The most common (42%) sterilization durations being 11 to 20 minutes and commonest (63%) sterilization temperatures were 131 to 135°C. Analysis of these results was very difficult. Relating the data to the packaging method, it appeared that four respondents processed their unwrapped instruments using sterilization time less than 15 minutes at 121 to 128°C, and 14 processed the wrapped instruments less than 20 minutes at 121 to 128°C. Five respondents processed wrapped instruments less than 10 minutes at 130 to 137°C. Thus, at least 23 (13%) of the respondents were using sterilization conditions below the recommended standards. About 11% of the respondents reported sterilization durations exceeding 40 minutes, which may include the total cycle duration instead of holding duration. Although improper sterilization durations and temperatures is one of the major reasons for sterilization failure, a previous study did not relate the sterilization conditions to spore test failures. In our study, four of 13 respondents who failed the initial spore test used incorrect duration/temperature conditions for sterilization of wrapped instruments.

**Sterilization monitoring and autoclave maintenance**

Sterilization effectiveness depends on rigorous quality assurance programs, since it is not possible to test all instruments to confirm sterility. In this study, 62% of respondents used chemical indicators and only 4% used BIs. In contrast to some states in the US, regular biological monitoring using spore tests is not mandatory in Hong Kong. Not surprisingly, 96% of our respondents did not use them to monitor sterilization, notwithstanding the fact that 86% reported routine biological monitoring of sterilizers was necessary. Use of chemical indicators was also unsatisfactory in our study. For those using chemical indicators, only 52% used them on every load (as recommended by some authorities). As in the UK, there is a regulation in Hong Kong that mandates an annual check of pressurized systems such as autoclaves by qualified personnel. However, compliance with this regulation appears low, as reflected by the fact that 62% of the autoclaves used by our respondents were older than 1 year and had no maintenance service within the last year. Thus, sterilization monitoring and sterilizer maintenance practices are far from ideal in Hong Kong. Sterilization assurance programs should be promoted and possibly enforced by stringent regulations.

**Spore tests results**

Thirteen (7%) of 175 autoclaves failed the initial spore test. Of these, two (1%) failed the repeated test. Direct comparison of the findings from this study with previous studies is difficult because of methodological differences. However, the initial spore test failure rate of 7% is comparable to rates in the UK (2%) and Ireland (13%). The number of autoclaves that failed to sterilize the spore ampules was too low for appropriate statistical analysis or comparison with practice profiles.
Conclusion

One of the most fundamental aims of a dentist is to ensure their own safety, as well as that of their staff and patients, and in so doing offer protection from the ever-present danger of cross infection. Instrument sterilization is among the most important steps in achieving this goal. Our study indicates that sterilization failure of autoclaves does occur in private dental practices in Hong Kong; 7% of the 175 tested autoclaves failed to sterilize spore ampules, and the majority of practices did not monitor autoclave performances regularly. Thus contaminated instruments could have been used on some patients.

One autoclave failure is too many, when the potential risk of cross infection is considered. Therefore all autoclaves used in dental practices in Hong Kong should be regularly checked, and their effectiveness routinely validated by testing with BI. Knowledge about the proper use of autoclaves should be improved and the importance of sterilization assurance through regular maintenance and monitoring must be stressed.

In the context of this study, it appears that the postal spore test could be a useful means of monitoring sterilization performances in private practices in Hong Kong.

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Appendix  Questionnaire

A study on autoclave performance in private dental practices in Hong Kong

PART I

1. Country where you graduated from dental school: ___________________
2. Year of graduation:  ___________________
3. How would you describe your practice? (Please tick one only)
   □ Partnership, group practice
   □ Self-employed, solo practice
   □ Associate, group practice
   □ Non-government organization
   □ Health Maintenance Organization
   □ Others_____________________
4. What is the main stream of your practice? (Please tick one only)
   □ General dentistry
   □ Endodontics
   □ Oral and maxillofacial surgery
   □ Orthodontics
   □ Periodontology
   □ Pediatric dentistry
   □ Prosthodontics
5. Have you attended any postgraduate CME course on infection control in the last year?
   □ Yes
   □ No
6. Have your dental surgery assistant(s) received formal training in the use of sterilizers?
   □ Yes
   □ No
7. Do you think that routine biological monitoring of sterilizers is necessary?
   □ Yes
   □ No
8. What type of sterilizer do you mainly use in your dental office?
   □ Gravity displacement steam autoclave (the most simple table top autoclave)
   □ Vacuum-assisted steam autoclave (contains a pre-vacuum phase to make steam penetrate more effectively)
   □ Dry heat oven
   □ Unsaturated chemical vapor sterilizer
   □ Not known
   □ Others_____________________

If you do not use autoclaves in your office, this is the End of the questionnaire.
Please return this questionnaire by the return envelope as soon as possible.

PART II

For those who use autoclaves in your office
Please  1. perform the spore test and
       2. complete questions 9-18.

9. Please write down the name of the manufacturer and model no. of the tested autoclave used for the spore test:

10. What packaging material and method was used for the spore test during the test cycle? (Please tick one only)
    □ None/unwrapped
    □ A perforated tray
    □ A non-perforated tray
    □ A sterilization pouch
    □ A perforated tray with wrapping paper
    □ A container with filter system
    □ Others_____________________

11. What was the sterilization time and temperature of the autoclave during the spore test? (sterilization time means the holding time for sterilization, excluding warm up and drying time.)
    ______________________ minutes at _____________________ oC

12. How many years has the autoclave been used?
    □ ____________________ year(s)
    □ Not known
### Appendix (continued)

13. Does your practice use chemical indicators (e.g. color change in autoclave tape) for monitoring of sterilization?
   - Yes, (please tick) on every 
     - load, day, week, or others _______________
   - No

14. Does your practice use biological indicators (such as the one sent to you) for monitoring of sterilization?
   - Yes, (please tick) on every 
     - day, week, month, or others _______________
   - No

15. Did the autoclave receive any maintenance service within 1 year prior to this survey?
   - Yes
   - No

16. On average, how many patients do you usually treat during a working day?
   - _______________ patient(s) per day

17. On average, how many cycles of sterilization does the tested autoclave operate during a working day?
   - _______________ cycle(s) per day

18. Contact telephone number _______________(we will contact you only if the spore test is positive)

Please return this questionnaire together with the two biological indicators by the return envelope as soon as possible. Thank you.