IN BRIEF

- Provides the results of a national survey investigating the use of benchtop steam sterilisers in dental practice.
- Highlights shortcomings in the operation of sterilisers.
- Highlights the testing of sterilisers in dental practice.

VERIFIABLE CPD PAPER

Sterilisation of re-usable instruments in general dental practice

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Objective To examine the methods used for sterilisation of re-usable instruments in general dental practice, including the installation, commissioning and testing of benchtop steam sterilisers.

Materials and methods This was an observational study in which the policies and procedures for sterilising instruments were viewed directly by trained surveyors at practice premises. Information relating to the installation, commissioning and testing of benchtop steam sterilisers was also collected by interview and observation of records. Data were recorded onto a standardised data collection form prepared for automated reading.

Results Data were available from 179 surgeries surveyed. Dental practices reprocess a range of instruments from critical to non-critical. The most common type of benchtop steam steriliser is a type N, or bowl and instrument (B&I) steriliser (88%). The remainder were type B, or vacuum sterilisers, though one surgery had access to a hot air steriliser. Sterilisers were usually installed by manufacturers or suppliers (69%). Only 51% of sterilisers were tested on installation and 26% were commissioned, of which 38% were tested to SHTM 2010 standard. In most cases it was difficult to determine from the documentation available whether daily, weekly, quarterly or annual testing was undertaken in accordance with recognised standards. Written instructions for the operation of the steriliser were unavailable in 61% of practices. Insurance cover for pressure vessels was available in 79% of surgeries with a B&I steriliser. In many instances there was inadequate separation of clean and dirty areas for segregating processed from unprocessed instruments. Ninety-six percent of surgeries did not have a procedure for the identification and traceability of instruments used on patients. There was no documentation of staff training in the use of sterilisers in 90% of surgeries.

Conclusion There has been significant uptake of the use of steam sterilisation to reprocess used dental instruments. However, there are significant shortcomings at various stages of the process, including installation, commissioning and periodic testing of sterilisers. These potentially compromise safety and the time, money and effort currently put into sterilising dental instruments. Complicit in these deficiencies are the manufacturers and suppliers of equipment that is inadequately installed and tested. There is a need for enhanced education and training in the use of sterilisers and the management of the process at all levels, from supplier to user. Improved access to appropriate technical advice on decontamination would also be a major benefit for the profession.

INTRODUCTION

Steam sterilisation is the preferred method of sterilisation for re-usable dental instruments. This method has several advantages including excellent microbial lethality, cost-effectiveness, lack of toxic residues and the ability to be effectively physically controlled and monitored. However, for the process to be effective the instrument surface must be in direct contact with dry saturated steam at the required temperature, for the requisite time, in the absence of air. It is recommended that the highest temperature compatible with the load is used (134-137°C at 2.25 bar for a minimum hold time of three minutes).[1] To achieve these parameters it is essential that the steriliser is installed, commissioned and validated before use. Following commissioning, the machine must be periodically tested to ensure that the parameters established at installation are still valid.[1-4]

Steam sterilisation has been widely used in UK dental practices for many years. In 1989 it was reported that hand instruments were sterilised in 97% of UK practices.[5] By 1998 all respondents (n = 401) in a UK postal survey reported use

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Online article number E16
Refereed Paper – accepted 24 January 2007
DOI: 10.1038/bdj.2007.912

of an autoclave,[6] although in a more recent survey involving 372 respondents in the UK, only 82% of dental practitioners reported using an autoclave.[7] The remainder of respondents used either a hot air oven (10%) or used a central sterile service department or other facility (8%). However, although steam sterilisation is used so widely in general dental practice, there is evidence that the equipment is not being tested, monitored or maintained correctly.

The use of bacterial spores as biological indicators (BIs) for monitoring steam sterilisers has been deprecated by UK health departments since 1957. The preferred practice is to employ physical monitoring of the required time/temperature conditions. Biological indicators do not give a result within the time required to prevent the use of a non-sterile item. In addition, the use of a BI does not establish that there is a 10^{-6} or lower probability of a surviving micro-organism. If the BI is killed it does not prove that sterilisation was satisfactory – although if it grows it proves that it was not. Nevertheless there are territories where the use of BIs is still accepted practice. Failure rates of BI tests in general dental practice have ranged from 2-33% in various countries.[6,8-11] More recently, a failure rate of 2% of autoclaves tested was found, with the plastic spore ampoules being melted in three of the sterilisers tested.[7] These findings are not unique to dental practice, since independent audit has demonstrated that in central sterilisation departments, as well as in primary care facilities, the reprocessing of medical devices has been sub-optimal.[12,13]

Sterilisation of critical devices is widely accepted as essential when re-using medical devices. For semi-critical devices, sterilisation is the preferred method.[14-17] Dental instruments are classified as 'medical devices'.[18] The importance of sterilisation as part of the overall process of instrument decontamination has come under increased scrutiny in recent times, following the appearance of vCJD in the UK population and elsewhere. Whilst the cleaning and cleanability of medical devices are important elements of reprocessing, the sterilisation process is also central in reducing the risks of onward transmission of vCJD and other infectious agents.[19]

Previous studies of sterilisation of instruments in general dental practice have relied on postal questionnaires or inspection of relatively few premises.[20] There have been no large-scale studies that have involved visits to dental practices to view the operation of benchtop steam sterilisers, review at first hand the documentation accompanying these machines and interview the staff operating them. The aim of this study was to survey the operation of benchtop steam sterilisers in general dental practice and review the documentation associated with their use.

MATERIALS AND METHODS

Survey methodology

This has previously been reported in detail.[21] In brief, the study population comprised all general dental practitioners in Scotland with a National Health Service (NHS) list number (located in 837 different practices). This list was the basis for randomly selecting practitioners to survey. A two-stage process was employed to identify which surgeries were to be surveyed, using a proportional stratified random sampling method. First, practices were randomly selected in proportion to the distribution of practices within each of the health boards.

Table 1 Summary of the information on purchasing, installation, testing and operation of sterilisers obtained from the dental surgeries

	Yes	No
Purchasing of sterilisers		
Written specification generated prior to purchase	14%	86%
Equipment purchased via verbal order with dental supply house	89%	11%
Surgery had access to Authorised Person (Sterilizers)*	5%	95%
Installation, commissioning and validation of steriliser		
Steriliser tested on installation	51%	49%
Steriliser commissioned	26%	74%
Steriliser commissioned to SHTM 2010 standard	10%	90%
Steriliser installed by manufacturer	39%	61%
Steriliser installed by supplier	30%	70%
Steriliser installed by primary care trust or health board	3%	97%
Steriliser installed by other (eg dentist or dental nurse)	27%	73%
Periodic and daily testing		
Type N steriliser tested in accordance with SHTM 2010	15%	85%
Type B steriliser tested in accordance with SHTM 2010	13%	87%
Validation record signed by Authorised Person	0%	100%
Type N steriliser underwent daily safety tests	35%	65%
Type B steriliser underwent daily steam penetration test	15%	85%
Chemical and biological indicators		
Integrating chemical indicators used in steriliser	39%	61%
Integrating chemical indicators used in steriliser for every load	17%	83%
Biological indicators used in steriliser	1%	99%
Servicing and maintenance of sterilisers		
Maintenance contract held for steriliser	90%	10%
Type N steriliser serviced regularly	92%	8%
Type N steriliser serviced annually	88%	12%
Type N steriliser serviced quarterly	63%	37%
Valid portable appliance test certificate available	53%	47%
Weekly safety checks performed	25%	75%
Pressure systems safety regulations		
Insurance cover for pressure vessels available: surgeries with a Type N steriliser	79%	21%
Insurance cover for pressure vessels available: surgeries with a Type B steriliser	60%	40%
Written scheme of examination approved by a Competent Person (Pressure Vessels) available: surgeries with a Type N steriliser	61%	39%
Written scheme of examination approved by a Competent Person (Pressure Vessels) available: surgeries with a Type B steriliser	65%	35%

*An individual who is registered by the Institute of Healthcare Engineering and Estates Management and is qualified to provide independent auditing, advice, review documentation and test data on decontamination equipment[2,3]

Table 1 Summary of the information on purchasing, installation, testing and operation of sterilisers obtained from the dental surgeries

Continued from previous page		
	Yes	No
Annual visit from a Competent Person (Pressure Vessels): surgeries with Type N steriliser	63%	37%
Annual visit from a Competent Person (Pressure Vessels): surgeries with Type B steriliser	55%	45%
Operation of sterilisers		
Written instructions for operation of the steriliser available	39%	61%
Written instructions on correct loading patterns for the steriliser provided	19%	81%
Records kept of user checks undertaken of the steriliser	33%	67%
Type N steriliser fitted with datalogger	23%	77%
Type B steriliser fitted with chart recorder or datalogger	60%	40%
Procedure for identification and traceability of instruments used on patients	4%	96%

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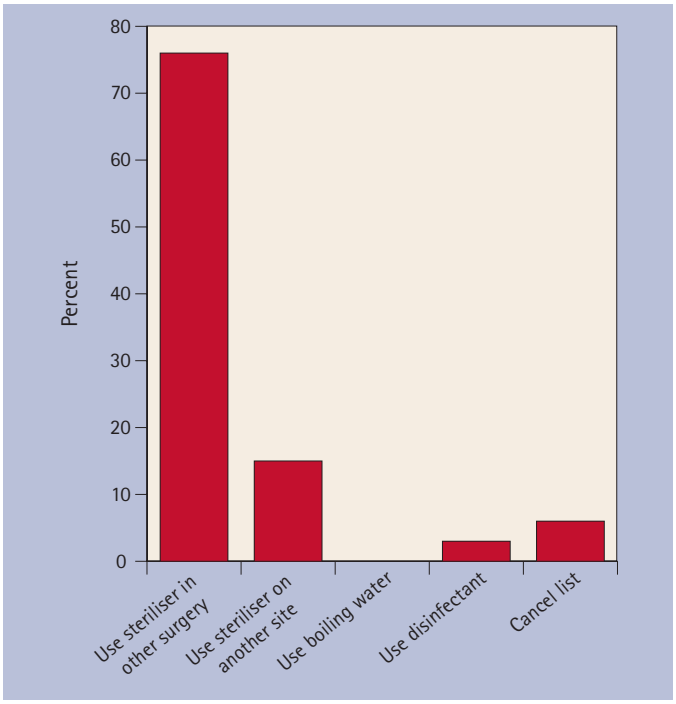

Fig. 1 Action taken by surgery when steriliser out of service

Then, if there was more than one dentist within a selected practice, simple random sampling was used to identify a single dentist to be approached within the practice. The surgery that the identified dentist worked in and its associated decontamination facilities were the subject of the survey. A total of 184 surgeries were surveyed, with usable data obtained from 179 surgeries.

Data collection

Each surgery was surveyed by a team of two: an infection control/decontamination expert and an experienced dental practitioner. The survey team interviewed the dental practitioner and dental nurse, reviewed documentation relevant to the survey and recorded the physical layout of the premises. The operation of a benchtop steam steriliser, usually undertaken by the dental nurse, was viewed directly by a member of the survey team. All relevant data were recorded onto data collection forms prepared for automated reading.[21] The survey visits ran from January 2003 until the end of March 2004.

Technical requirements and guidance

The data collection forms of the survey were based on a number of technical requirements and guidelines.[22-29] In addition, to ensure that appropriate facilities and management processes were in place within surgeries, data were collected to examine compliance with a number of legal requirements. The latter included the Consumer Protection Act,[30] the Medical Devices Regulations 2002,[31] the Health and Safety at Work Act 1974,[32] Management of Health and Safety at Work Regulations 1992,[33] Provision and Use of Work Equipment Regulations 1998[34] and the Pressure Systems Safety Regulations 2000.[35]

RESULTS

Treatment procedures undertaken

There was a wide range of treatment procedures undertaken in the surgeries surveyed. The most common procedures in the 179 surgeries were routine conservative dentistry, fixed/removable prosthodontics and endodontics, all undertaken by 97% of surgeries. Other common procedures were extractions (96%), routine periodontal treatment (94%) and surgical extractions (88%). Less common procedures included orthodontics (55%), apicectomies (54%), mucosal biopsies (36%), periodontal surgery (28%) and placement of dental implants (8%). Many of these procedures will involve the use of instruments classified as critical, which must therefore be sterilised before re-use and should be sterile at the point of use.

Types of steriliser

There are two types of steriliser in common use in dental surgeries. These are:

(i) Type N sterilisers (also known as bowl and instrument (B&I), unwrapped instrument and utensil sterilisers, or natural displacement sterilisers)
(ii) Type B sterilisers (also known as vacuum benchtop sterilisers).

The majority of the surgeries surveyed (88% (n = 160)) used Type N sterilisers. The remaining surgeries (11% (n = 20)) used Type B sterilisers, with one surgery also having access to a hot air steriliser. The Type N sterilisers were aged between 1 and 19 years (median 5 years), whilst the Type B sterilisers were between <1 and 5 years old (median 2 years).

Purchasing, installation, testing and operation of sterilisers

Findings related to the purchasing, installation, commissioning, validation, periodic and daily testing, servicing, maintenance and operation of sterilisers in the dental surgeries are summarised in Table 1. The types of instruments reprocessed in Type N sterilisers are summarised in Table 2. If the steriliser were unavailable, for example on account of a mechanical breakdown, then the surgery took the actions shown in Figure 1.

Table 2 Types of instruments reprocessed in Type N sterilisers

Type of instrument	Number
Simple planar instruments	165
Jointed instruments	164
Hollow instruments	140
Bowls	68
Dental handpieces	160
Brushes	79
Prophylaxis brushes	60
Matrix band and holder	130
Burs	153
Endodontic files	144

Table 3 Summary of information obtained from the dental surgeries on packaging and storage of instruments pre- and post-sterilisation

	Yes	No
Packaging prior to sterilisation		
Instruments packaged before sterilisation in a Type N steriliser	28%	72%
Instruments packaged before sterilisation in a Type B steriliser	60%	40%
Instruments packaged with a double layer before sterilisation in a Type B steriliser	10%	90%
Packaging materials purchased against European standards	79%	21%
Pre-sterilisation packaging (intended to be single-use) re-used	9%	91%
Packaging prior to sterilisation		
If packaging instruments prior to sterilisation, packaging area clearly segregated from cleaning and disinfection areas	20%	80%
Packaging after sterilisation		
Instruments packaged for storage after sterilisation	70%	30%
Instruments packaged after sterilisation in a Type N steriliser	55%	45%
Instruments packaged after sterilisation in a Type B steriliser	50%	50%
Post-sterilisation packaging took place in a dedicated area	37%	63%
Storage after sterilisation		
Sterilised items stored in cupboards	51%	49%
Sterilised items stored in drawers	86%	14%
Sterilised items stored on shelves	32%	68%
Sterilised items stored on work surfaces	34%	66%
Post-sterilisation storage in same area as patient treatment	91%	9%
Post-sterilisation storage in same area as decontamination area	48%	52%
Post-sterilisation storage area visibly tidy and well organised	89%	11%
Sterile packs and sterilised instruments issued in strict rotation	19%	81%

Steriliser water

Figure 2 summarises the types of water that were being used to replenish the reservoirs of the sterilisers. The frequency of draining and replenishing the steriliser reservoir is shown in Figure 3.

Packaging and storage of instruments pre- and post-sterilisation

Results related to the packaging of instruments prior to and after sterilisation and the storage of items after sterilisation are summarised in Table 3. The types of packaging used when wrapping instruments before sterilisation in a Type N steriliser are shown in Figure 4.

Staff training for use of sterilisers

Findings related to the training of staff operators of the sterilisers within the surgeries are summarised in Table 4.

DISCUSSION

The majority of procedures performed in dental practice involve devices that are classified as critical or semi-critical, since they frequently breach the patients' mucosa or gingivae. There have been a number of reported transmissions of hepatitis B in dentistry,[36-41] although it has been difficult to prove or disprove direct links associated with failure of decontamination of dental instruments. Nevertheless, there is clear potential for cross-infection to occur if certain basic principles are not adhered to. This is supported by *in vitro* evidence of the potential for transmission.[42-48]

In principle, many dental instruments that fall into a semi-critical or non-critical category could be reprocessed for subsequent use by less stringent methods, for example high-level disinfection. However, segregation of instruments in a busy dental practice into different categories destined for different reprocessing techniques is unlikely to be safely achieved and is therefore best avoided. The most practical and safe method of operating is to clean and steam sterilise all re-usable instruments. Many dental instruments are categorised as critical devices and as such should be sterile at the point of use. The results of this survey demonstrate that the majority of critical devices in use in dentistry have been through a steam sterilisation process (albeit inadequately validated) but are not sterile when used. If dental practices were to adopt the approach of sterile instruments at point of use for critical devices (as in other healthcare sectors) this would involve a large-scale change in the methods of decontaminating dental instruments (use of automated washer-disinfectors and vacuum sterilisers) and would require substantial financial commitment in primary dental care.

This survey, which has involved observing the operators of benchtop steam sterilisers, reviewing associated documentation and interviewing staff, has produced robust data on the operation of benchtop steam sterilisers in general dental practice in the UK. It confirms and adds to earlier work using postal questionnaires[7] that whilst benchtop steam sterilisers are in place in the majority of UK dental practices (and present in all the practices in this survey), they are not being validated, tested or maintained to the required standards.

There are a number of areas of concern arising from this survey. A fundamental principle of any sterilisation method is that it should be carried out using a validated process. This is

because it is not practicable to test instruments emerging from the steriliser for sterility prior to use. It is necessary to establish that the sterilisation process, when correctly implemented, will consistently and reliably produce the required outcome; this is demonstrated during the validation process.[2,3] The validation process may be defined as 'a documented procedure for obtaining, recording and interpreting the results needed to show that a process will consistently yield a product complying with predetermined specifications'. Validation is considered as a total process, which consists of commissioning (a process of installation checks, tests and operational tests) followed by performance qualification (the process of obtaining and documenting evidence that the equipment as commissioned will produce an acceptable product when operated according to process specification).[2,3] The latter consists of tests designed to show that sterilisation conditions are achieved throughout a typical load. The results of these tests should be performed and submitted by a qualified Test Person (Steriliser), audited by an Authorised Person (Steriliser) and signed by the user to accept the steriliser as suitable for use.[2,3] The results from our study suggest that this process is not usually undertaken for benchtop steam sterilisers in general dental practice. Most practitioners were unaware of the role of the Authorised Person (Steriliser) (an individual who is registered by the Institute of Healthcare Engineering and Estates Management and is qualified to provide independent auditing, advice, review documentation and test data on decontamination equipment[2,3]) or Test Person (Steriliser) (an engineer appropriately qualified to perform validation and periodic testing of sterilisers) in this process, or their qualification requirements.[2] The lack of documentation supplied by the manufacturers implies that they also may be unaware of appropriate standards required for the installation and testing of benchtop steam sterilisers. Consideration should be given to a scheme of independent accreditation for suppliers, to ensure that the relevant regulatory procedures are followed. As well as ensuring that a new steriliser is functioning correctly, the validation process documentation provides useful evidence in the event of an adverse incident. The validation process will also help practitioners to fulfil their obligations under the Consumer Protection Act,[30] Health and Safety at Work Act[32,33] and in particular the Provision and Use of Work Equipment Regulations 1998.[34]

All surgeries surveyed had a benchtop steam steriliser, but the documentation, testing and operation of these machines were frequently unsatisfactory, increasing the risks of an adverse event occurring. The daily tests required to be performed on a benchtop steam steriliser depend on the type of steriliser used. For the most common type of steriliser (Type N), users are required to undertake safety tests and note whether the sterilisation cycle was within the required parameters, whether the steriliser controller indicated a pass or fail cycle, and the date, cycle number, type of load and identity of the operator. To demonstrate the efficacy of a Type B steriliser it is necessary to perform a daily steam penetration test (analogous to a Bowie Dick test performed on porous load sterilisers). This test demonstrates that the steam will penetrate rapidly and evenly into a test device that is at least as difficult to sterilise as the intended load. The test piece and the indicator should be as specified in BS EN 867 Part 5.[23] Further to such daily tests, the manufacturer's routine maintenance tasks must also

Table 4 Summary of information obtained from dental surgeries on staff training for use of sterilisers

	Yes	No
Documentation available of staff training in steriliser operation	10%	90%
Training for use of steriliser provided by observed practice	88%	12%
Training for use of steriliser provided by demonstration	93%	7%
Training provided on limitations of types of load	27%	73%
Training provided on correct loading procedures for steriliser	33%	67%

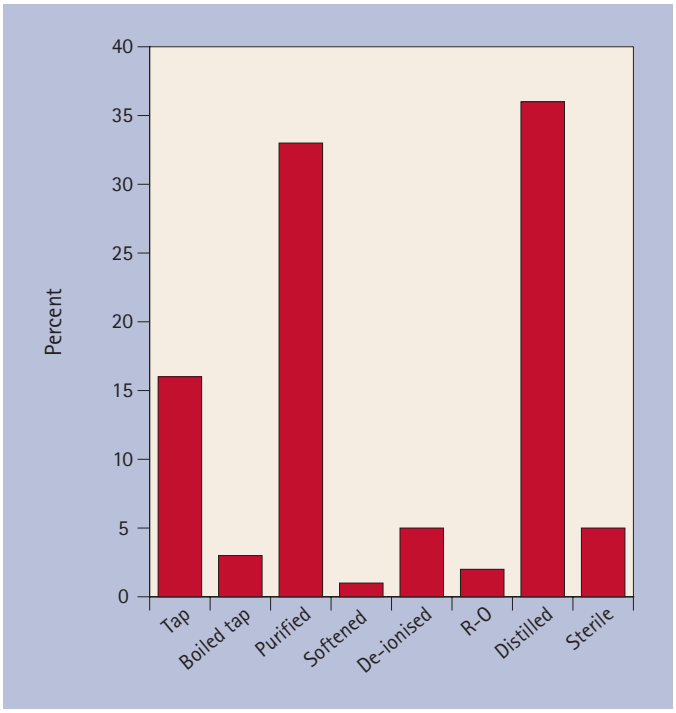

Fig. 2 Water used in sterilisers

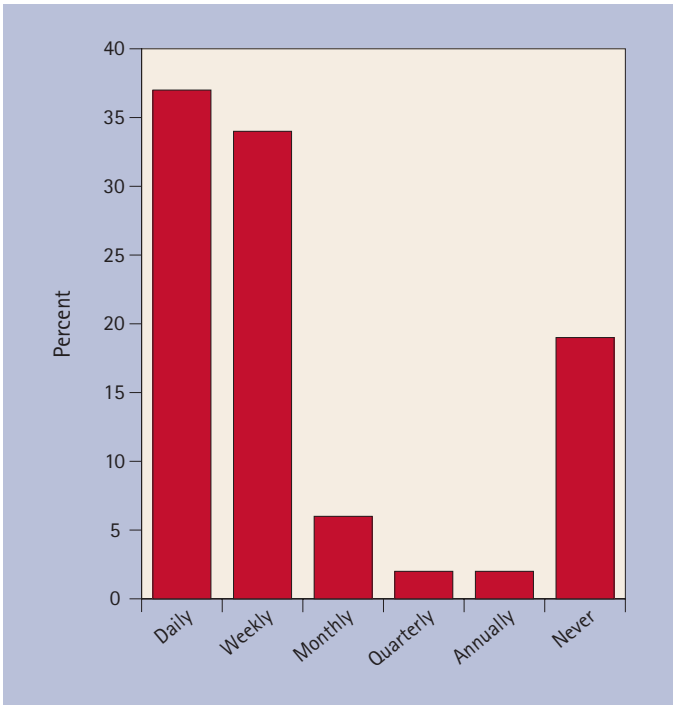

Fig. 3 Frequency of draining of steriliser reservoir

be performed at the specified intervals. In particular, weekly checks should be undertaken on the door interlocks and door seals, which should be replaced if they leak or show signs of wear. The lack of periodic and daily testing being undertaken on the sterilisers is a fundamental lapse in the quality control of the steam sterilisation process and has identified both training requirements and the need for formal recording of tests that are undertaken.

Since steam sterilisers require a pressurised system to work effectively, their use and maintenance is covered by the Pressure Systems Safety Regulations (PSSR) 2000.[35] These regulations protect users and others from the risk of injury if the pressure vessel fails. The practitioner is responsible for compliance with the PSSR. Requirements include adequate training of the steriliser user, maintenance and a written scheme of examination. The written scheme of examination is certified by a Competent Person (Pressure Vessels).[2,3] Due to the particular hazards associated with pressurised steam, users must have insurance to cover the associated risks. This is usually third party liability insurance cover (standard practice insurance does not usually cover these risks). Insurers normally provide a written scheme of examination and often have their own Competent Person to carry out the pressure system inspection. Failure to ensure the safety of a pressure system can be a criminal offence and this study has identified a significant number of practices that were unaware of the legal requirement for pressure vessel insurance if a steam steriliser is in use.

There is continued debate over whether vacuum or non-vacuum benchtop steam sterilisers should be used to sterilise dental handpieces. Clearly the majority of practitioners in this survey were using B&I sterilisers. It is recommended by the manufacturers of benchtop steam sterilisers and others[1–3,16] that wrapped and lumened devices should not be reprocessed in B&I sterilisers. The issue is confounded by the fact that whilst many handpiece manufacturers have validated their handpieces for the sterilisation process, most have no cleaning validation data, as recommended in more recent standards.[49] Without adequate pre-cleaning it is unlikely that dental handpieces can be reliably sterilised.

The survey identified confusion in some practices about the operational differences between vacuum and non-vacuum steam sterilisers. Traditional Type N (natural displacement or B&I) benchtop steam sterilisers may fail to sterilise lumened items or packaged devices due to failure to remove air from the steriliser chamber.[1] If packaged devices are to be sterilised they should be processed through a Type B steriliser, which provides forced air removal. However, some practices with Type B (vacuum) benchtop steam sterilisers were failing to perform the necessary daily tests,[50] negating the advantages of owning and operating such a machine. Other practices with Type N (B&I) sterilisers were wrapping instruments prior to sterilisation, with attendant risks of sterilisation failures. In addition to issues related to instrument packaging, the study also identified poor practice in relation to the quality of water used in the steriliser and the frequency with which it was changed. All of these findings reflect the paucity in training of the users and operators of benchtop steam sterilisers and access to appropriate technical advice, which should be urgently addressed. It is a requirement of the Provision and Use of Work Equipment Regulations 1998[34] that everyone who operates, supervises or manages work equipment must be adequately trained. Details of training, such as skill level, competencies tested and date undertaken, should be recorded.

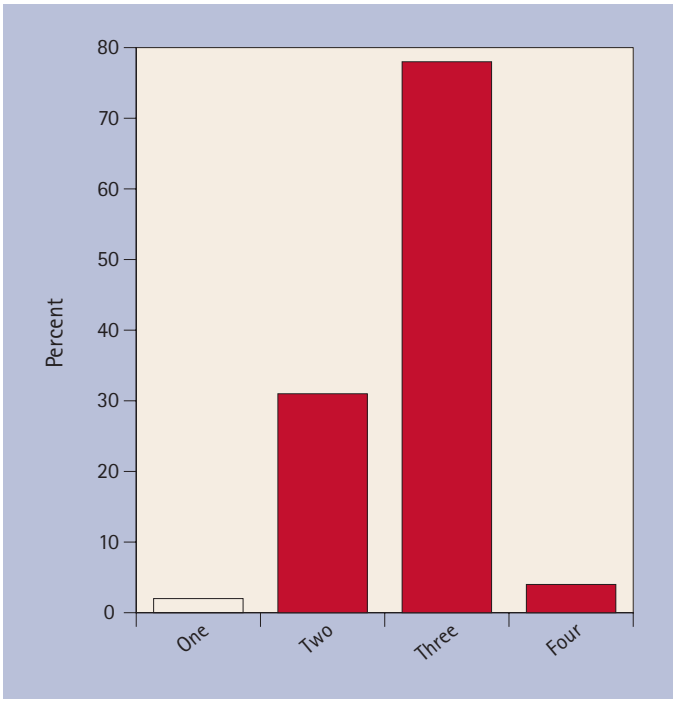

Fig. 4 Type of packaging used when wrapping instruments before sterilisation in a B&I steriliser

In conclusion, whilst it is reassuring that all practices surveyed were using benchtop steam sterilisers, the manner in which they had been installed, tested and operated would provide only limited assurance in the event of an adverse incident. The lack of documented adverse incidents should not be a signal for complacency, since the lack of active surveillance for transmission of infection may preclude detection of a breakdown in infection control within a dental practice. There is a requirement to be vigilant against a wide range of both common and unusual infectious diseases. It is imperative that the fundamental principles underpinning the effective use of steam sterilisation equipment, as outlined in the many technical guidance documents, are applied in general dental practice.[49] In the future, monitoring of decontamination standards in general dental practice may fall to appropriate primary care trusts and health boards. However, it is increasingly apparent that many dental team members are inadequately trained and insufficiently supported by appropriately qualified experts in the field of decontamination sciences. Much remains to be done to support practitioners in this field, to improve patient and staff safety and to facilitate cost-effective instrument decontamination in dental practices.

This study was funded by the Scottish Executive Health Department. Funding for the training of the survey team members was provided by NHS Education for Scotland. The authors thank the members of the survey teams and the dental practitioners and nurses who agreed to be surveyed.

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