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Research Article

EVALUATION OF AUTOCLAVE EFFICIENCY USING DIGITAL STERILIZATION MONITORS & TEMPERATURE STRIP INDICATORS

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ABSTRACT

Introduction: Autoclaves are the most dependable and effective mode of sterilization of dental equipment. Various tools are available to assess the performance of the autoclave (physical, chemical and biological indicators). Among these, advent of digital sterilization monitors have created a new window of opportunity to verify the efficacy of the autoclave functioning. An attempt was made to see if the digital indicators can be an effective replacement to the most commonly used mode of autoclave testing i.e. temperature indicator strips.

Objectives: To evaluate & compare autoclave efficacy using digital sterilization monitors and temperature indicator strips.

Methods: 5 steam sterilizers in the institute were randomly selected for the study. The chosen autoclaves are emptied and prepared to run a full cycle with the digital monitor and the temperature indicator strips placed inside. The results of the digital indicators are then compared with that of the biological indicators for further analysis.

Results: 3 out of the 5 autoclave readings showed that the temperature strip colour changes were not correctly matching with a successful sterilization cycle. The readings of digital monitors showed that only 2 out of 5 autoclaves were successfully completing a sterilization cycle.

Conclusions: The temperature strip indicators were found to be inconclusive in evaluating the efficacy of the autoclaves. When verified with digital monitors, the front load type of autoclaves were found to be more effective in completing successful sterilization cycles in comparison with steam sterilizers.

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INTRODUCTION

Infection control practices have come under increasing public scrutiny over the last decade in the light of significant medical problems associated with the acquisition of blood borne pathogens following both medical and dental procedures.¹ According to the Centers for Disease Control, dental instruments that are classified as critical and semi-critical instruments and are heat stable should be sterilized after each use by steam under pressure (autoclaving), dry heat, or chemical vapor².

Autoclaves have evolved to be the most reliable mode of sterilization for dental instruments over the last decade. A number of tools are available to assess the performance of the autoclave; these include physical, chemical and biological indicators. It is important to note that these indicators will only respond to time, temperature and moisture conditions, and not to organic load³.

Recent advances in science and technology have helped in developing highly sensitive digital indicators which mark the next step in research towards better monitoring of sterilization procedures especially autoclaves. The digital indicators are proclaimed to be very sensitive and accurate in recording minute shift of temperatures within the autoclave. So, there lies intrigue to compare the digital monitors with the more commonly used physical or chemical indicators of sterilization to establish the efficacy of the steam sterilizers (autoclaves). Hence an attempt has been made in this study to compare the efficacy of autoclaves using digital sterilization monitors and temperature indicator strips.

Objectives of the study

1. To evaluate autoclave efficacy using digital sterilization monitors.
2. To evaluate autoclave efficacy using chemical indicator strips.

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3. To compare the digital sterilization monitor readings with those of the temperature indicator strips.

MATERIALS AND METHODS

A study was conducted to test the efficacy of autoclaves using digital sterilization monitor readings and temperature indicator strips.

Source of Data

Study was conducted in all the departments of Coorg Institute of Dental Sciences, Virajpet Karnataka. There are a total of 13 departments in the institute which utilize steam sterilizers. Temperature readings of 5 such autoclaves were randomly selected for the study.

Chemical Indicator

The commonly used indicator for testing the autoclaves is the Temperature Indicator strips⁴ (3M Autoclave Steam Indicator Tape®). The color-changing indicator of tape is lead carbonate based, which decomposes to lead oxide. To protect users from lead -- and because this decomposition can occur at many moderate temperatures -- manufacturers may protect the lead carbonate layer with a resin or polymer that is degraded under steam at high temperature only. This tape was placed within the autoclave prior to running the cycle.

Digital Indicator

The Digital Sterilization Monitor (DS1922F®) is a precision, electronic-based solution designed to monitor and record the applied temperature profile during an autoclave sterilization cycle.⁵ The device when placed inside an autoclave, measures and logs temperature by recording data into the device memory. Once the sterilization cycle is complete, the device is simply removed from the sterilization chamber and docked into the USB reader accessory to download the captured data to a PC. Companion software then displays the temperature measurements, indicates whether the sterilization cycle was successful, and keeps a record of the data to satisfy regulatory and liability requirements. This device was kept inside the autoclave along with the temperature indicator strip in an empty autoclave for one full cycle to record the readings.

Inclusion Criteria: Only Autoclaves (steam sterilizers) used for sterilisation of dental instruments were selected for the study.

Exclusion Criteria: Sterilizers other than steam sterilizers (hot air oven, simple heaters, boilers, hot water bath, chemiclaves, etc) were excluded from the study.

Pilot study: The digital monitor was placed in a hot water bath for testing accuracy of the logger and matched with a thermometer reading. The findings of the test study proved that the digital monitor was accurate in measuring the temperature.

Ethical clearance: The study was approved by the Review committee of the Institutional Review Board of Coorg Institute of Dental Sciences, Virajpet.

Study Procedure: The chosen autoclaves are emptied and prepared to run a full cycle along with the digital monitor and the chemical indicator strips placed inside the empty autoclave. After the cycle is complete, the digital monitor and the chemical indicator strips were retrieved for analysis. After the

cycle was completed, both the temperature strips were recorded for color change while the digital indicators were connected to a PC for downloading the cycle results.

RESULTS

An evaluation of 5 selected autoclaves in Coorg Institute of Dental Sciences, Virajpet was done using the temperature strip indicators and digital indicators in the same sterilization cycles simultaneously. The readings were recorded after completion of the cycles in each of the autoclave. The test results of each cycle were noted as pass or fail by the strip indicators based on color change of the tape followed by results of the cycle determined by the digital indicators along with detailed temperature logs of each cycle.

3 out of 5 strips changed color to blackish brown indicating that only 60% of the sterilization cycles were successful. Only 2 out of 5 cycles were reported to be a pass when tested by the digital monitor indicating that either temperature was not high enough or the time was not long enough. The readings of each cycle are as follows:

Table 1 Evaluation of Sterilization cycle in selected autoclaves by temperature indicator strips and digital indicators

Sterilization Cycle	Temperature indicator strip result	Digital indicator result (Max. Temp.)	Time at Maximum temperature
Cycle 1	Fail (no colour change)	Fail (100 ^o C)	2 min 10 sec
Cycle 2	Fail (no colour change)	Fail (118.5 ^o C)	1min 20 sec
Cycle 3	Pass (Change of colour)	Fail (118 ^o C)	30 sec
Cycle 4	Pass (Change of colour)	Pass (121 ^o C)	18 min 10sec
Cycle 5	Pass (Change of colour)	Pass (121.5 ^o C)	15 min 10sec

DISCUSSION

An evaluation of 5 selected autoclaves in Coorg Institute of Dental Sciences, Virajpet was done using the temperature strip indicators and digital indicators in the same sterilization cycles simultaneously. 3 out of 5 strips changed colour to blackish brown indicating that only 60% of the sterilization cycles were successful. Only 2 out of 5 cycles were reported to be a pass when tested by the digital monitor indicating that either temperature was not high enough or the time at required temperature was not long enough.

The results showed that the temperature strip indicators were found to be inconclusive in evaluating the efficacy of the autoclaves compared to the digital monitoring devices. These findings were similar to those of *T. Tiller et al*⁶ who conducted a study using biological indicators (BI) and chemical indicators distributed throughout four loads of clean waste which were controlled for weight, volume, and density. Bacterial growth occurred in 18 out of 22 ampules, and chemical indicators failed in 19 out of 22 locations.

It was also in accordance with *J.B. Selkon et al*⁷ who indicated there was bacterial growth which went undetected in 3.3% of the sterilizing cycles, representing five distinct episodes of sterilization failure that passed unnoticed by the conventional controls of physical measurements and sterility testing; It was also in accordance with study by *Alex Chan et al*,⁸ who reported faulty autoclaves in clinics across Hong Kong due lack of monitoring using spore test rather than chemical tests. *Cheri-Ho Lee et al*⁹ also reported less than 10% accuracy with

chemical temperature change indicators when out of 21 indicators tested; only 2 appear to be capable of accurately integrating the time-temperature effect at temperatures between 240° and 270°F. These various comparisons suggest that physical and chemical indicators cannot be considered as conclusive evidence of successful sterilization in an autoclave.

The gold standard indicators used for sterilization evaluation in autoclaves according to literature are the biological indicators (*B.stearothermophilus* spores), but these indicators require 24 hours for the bacterial cultures to develop and would not yield immediate results.

The results of this study suggest, digital indicators are trust worthy, sensitive to minute temperature changes during the course of the sterilization cycle and more importantly yield immediate results, while chemical and physical indicators were found to be inconclusive and inaccurate in interpreting the success of a sterilization cycle. Digital indicators can also help in identification of probable defects of the autoclave like insufficient coil temperature, lesser amount of time at the appropriate temperature or even improper use by the operator. This is helpful in repair and maintenance of sterilization equipment on a periodic basis when used regularly.

Although there are significant advantages of using the digital indicators, there are a few limitations that need to be considered. Firstly, the digital indicators measure only time and temperature inside the autoclave but not the pressure levels. Secondly, there is probability of 1% error of temperature readings given by most of the manufacturers. However the error of temperature reading cannot differ from the final reading by more than 1-2° C. The health professionals, health assistants, nurses and autoclave operators in labs need to be trained about proper usage of sterilization equipment and long term maintenance of both autoclaves and digital indicators. Overall, it is safe to conclude that digital indicators are modern and accurate in testing autoclave cycles, time saving and yield immediate results. However further research with larger samples is required to reduce margin of error in time-temperature measurement on a second by second basis for specific details of the sterilization cycle and establish digital indicators of sterilization as the gold standard.

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