CHALLENGES IN SUBSEQUENT LOADS IN SATURATED STEAM STERILIZATION: COMPARATIVE STUDY OF PERFORMANCE

Testes desafio em cargas subsequentes na esterilização a vapor saturado: estudo comparativo dos desempenhos

Pruebas desafío en cargas subsecuentes en la esterilización a vapor saturado: estudio comparativo de los desempeños

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ABSTRACT: Objectives: To evaluate the performance of the challenges with chemical indicators commercialized in the monitoring of saturated steam sterilization in a hospital autoclave in cycles of 134ºC and 121ºC, and to analyze the performance efficiency of the challenges in the monitoring of the sterilization cycles. **Method:** Descriptive research. The data were collected on the evolution of the turn of the chemical indicators type 5 of the challenge package A*, chemical indicators type 6 of challenge package B* and chemical indicators type 6 of the helix device C*. The challenge packages were submitted to temperatures of 134ºC and 121ºC, following the interruption phases and total cycle time. **Results:** The data of the chemical indicators of the challenges were tabulated according to the time of exposure and the interruption of the cycles. A table shows the results of the evolution of the turn of the chemical indicators type 5 of the challenge package A*, type 6 of the challenge package B* and type 6 of the helix device type C*, submitted to the temperatures of 134ºC and 121ºC, according to the phases of interruptions and total cycle time. **Conclusion:** Packages containing A* and B* have chemical indicators of different types and presented similar results, and the difference between them was not conclusive. The helix device C* with type 6 indicator showed more precise performance in the monitoring of cycles at 134ºC and 121ºC.

Keywords: Sterilization. Surgical instruments. Cross infection.

RESUMO: Objetivos: Avaliar o desempenho dos testes desafio com indicadores químicos (IQs) comercializados na monitorização da esterilização a vapor saturado, em autoclave hospitalar, em ciclos de 134ºC e 121ºC e analisar a eficácia do desempenho dos testes desafio no monitoramento dos ciclos de esterilização. **Método:** Pesquisa descritiva. Foram colhidos dados sobre a evolução da viragem dos IQs tipo 5 do pacote desafio A*, IQs tipo 6 do pacote desafio B* e IQs tipo 6 do dispositivo tipo hélix C*. Os pacotes desafio foram submetidos às temperaturas de 134ºC e 121ºC, seguindo as fases de interrupções e tempo total de ciclo. **Resultados:** Foram tabulados os dados dos IQs dos testes desafio conforme o tempo de exposição e a interrupção dos ciclos. Encontram-se em tabela os resultados da evolução da viragem dos IQs tipo 5 do pacote desafio A*, tipo 6 do pacote desafio B* e tipo 6 do dispositivo tipo hélix C* submetidos à temperatura de 134ºC e 121ºC, de acordo com as fases de interrupções e o tempo total de ciclo. **Conclusão:** Pacotes contendo A* e B* possuem IQs de tipos diferentes e apresentaram resultados similares, não sendo conclusiva a diferença entre ambos. O dispositivo hélix C* com indicador tipo 6 apresentou desempenho mais preciso na monitorização de ciclos a 134ºC e 121ºC.

Palavras-chave: Esterilização. Instrumentos cirúrgicos. Infecção hospitalar.

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RESUMEN: Objetivos: Evaluar el desempeño de las pruebas desafío con indicadores químicos (IQs) comercializados en la monitorización de la esterilización a vapor saturado, en autoclave hospitalaria, en ciclos de 134ºC y 121ºC y analizar la eficacia del desempeño de las pruebas desafío en el monitoreo de los ciclos de esterilización. **Método:** Estudio descriptivo. Fueron recogidos datos sobre la evolución del viraje de los IQs tipo 5 del paquete desafío A*, IQs tipo 6 del paquete desafío B* e IQs tipo 6 del dispositivo tipo hélix C*. Los paquetes desafío fueron sometidos a las temperaturas de 134ºC y 121ºC, siguiendo las fases de interrupciones y tiempo total de ciclo. **Resultados:** Fueron tabulados los datos de los IQs de las pruebas desafío según el tiempo de exposición y la interrupción de los ciclos. Se encuentran en tabla los resultados de la evolución del viraje de los IQs tipo 5 del paquete desafío A*, tipo 6 del paquete desafío B* y tipo 6 del dispositivo tipo hélix C* sometidos a la temperatura de 134ºC y 121ºC, de acuerdo con las fases de interrupciones y el tiempo total de ciclo. **Conclusión:** Paquetes conteniendo A* y B* poseen IQs de tipos diferentes y presentaron resultados similares, no siendo conclusiva la diferencia entre ambos. El dispositivo hélix C* con indicador tipo 6 presentó desempeño más preciso en la monitorización de ciclos a 134ºC y 121ºC.
Palabras clave: Esterilización. Instrumentos quirúrgicos. Infección hospitalaria.

INTRODUCTION

The Material and Sterilization Center (MSC) consists of a space designated for the processing of dental-medical-hospital articles, that is, the cleaning, preparation, sterilization, packaging and distribution of materials for other hospital areas. The MSC is responsible for providing contamination-free materials to be handled in various hospital procedures. It is an indirect aid provided to the patient through the processing and sterilization of these materials, being as important as direct care (that practiced by the health team with the patient)[1].

The sterilization of dental-medical-hospital materials is a complex and very important process that provides reusable materials free from viable microorganisms, offering security to the professionals who handle them — and especially to the patient, their final user[1].

Sterilization is understood as the physical or chemical process which destroys or inactivates all life forms present in a specific material, especially microorganisms including bacteria, fungi (both in their vegetative and sporulated forms) and viruses[2].

For critical articles, the probability of survival is one surviving micro-organism for every 10^6 units processed. This criterion is expressed as 10^{-6} and is known as the level of sterility, conventionally verified in the laboratory as a sterility test[3].

The level of sterility can be determined as the number of accessible microorganisms that survive unit sterilization of the product under consideration. The definition of the operating parameters of the chosen sterilization method indicates the safety margin of the product or the possible failure of the system[2].

Considering that the absolute sterility of an article (100% of death) theoretically does not exist, it is of the utmost importance that the whole sterilization process be widely monitored[4].

Theoretically, a standard sterilization cycle of moist heat is divided into three phases or steps:

- Step 1: conditioning, in which air is removed from the inner chamber of the sterilizer and there is preheating of the load;
- Step 2: Exposure or sterilization, in which contact of the steam with the material occurs under controlled conditions of pressure and temperature to promote the death or inactivation of viable microorganisms;
- Step 3: drying, responsible for the removal of condensed steam from the interior of the load[5].

By destroying all life forms at temperatures between 121 and 134°C, the sterilization process by saturated steam under pressure is the most widely used method in the hospital environment. The times used in the cycles vary according to the chosen temperature and the instructions of the equipment manufacturers'[6].

In health institutions, the release of sterilized material for physical use is accompanied by the observation of the physical results of sterilization, alongside the verification of chemical and biological indicators[1].

The monitoring of the sterilization process by means of physical indicators is done through the printed recording of data regarding time, temperature and pressure of each cycle[7].

The biological indicator consists of a standardized preparation of bacterial spores designed to produce suspensions containing 10^6 spores per unit of filter paper. The method allows to ensure that the set of all critical sterilization parameters is adequate because, after the application of the

process, microorganisms are directly tested for their growth or the lack of it[7].

The biological indicator is a parameter to ensure that the level of sterility established for the product is achieved, conferring the certainty of sterility against the defined minimum safety margin of only one contaminated unit in 10^{-6} units of the processed product[2].

According to the latest version (11140-1: 2014) of the International Organization for Standardization (ISO), CIs are classified into six categories:

- Type 1: process indicator (external indicator for use in individual items and distinguishing processed from unprocessed materials, *e.g.*: zebra tape);
- Type 2: indicator for use in specific tests (*e.g.*: Bowie Dick test);
- Type 3: single parameter indicator (reacts only to one critical variable of the sterilization process);
- Type 4: multiparametric indicator (indicator for internal use in individual items, reacts to two or more critical variables of the sterilization process);
- Type 5: integrator indicator (indicator for internal use in individual items, responds to all critical variables of the sterilization process);
- Type 6: emulator indicator (indicator for internal use on individual items, responds to all critical variables of the sterilization process).

According to the Resolution of the Collegiate Board of Directors (RDC) No. 15, it is recommended to record the monitoring of physical indicators at each sterilization cycle. The use of the biological indicator should be done daily, in a challenge package available commercially or built by the MSC and positioned at the point of greatest challenge of the autoclave. Loads containing implantable materials must be processed with a biological indicator. It is recommended that the monitoring of the loading process subsequent to the biological test be performed in a challenge test package with CIs (type 5 or 6), according to the routine defined by the MSC[9] itself.

In order to ensure the effectiveness and quality of sterilization, it is incumbent upon the MSC's technical head of the health service to analyze and approve the indicators that best meet the process[9].

The test challenge package is a device used to evaluate the performance effectiveness of a sterilization process and should provide a challenge to the process equal to or greater than that of the most difficult item routinely processed[6].

Cycle monitoring can be done by the use of a ready test challenge package or performed by manual construction using cotton fields, a practice currently not recommended due to the difficulty of reproducibility of packages[6].

One type of commercially offered test consists of a porous, ready-to-use package that presents a challenge to the sterilization process. It has a type 5 or 6 CI with immediate reading after the process[9].

For the safety of the sterilization process, it is important that the steam is able to reach all surfaces of the instruments and penetrate into empty instruments. The European Committee for Standardization, CEN TC102, developed the propeller test to demonstrate steam penetration into empty devices. This method uses a long narrow tube[10].

A challenge test available in the market is the helix type (TST Load check BROWNE®, Leicester, UK). It is a reusable device with lumen, made of Teflon with 1.5 m in length and 2.0 mm in internal diameter, and a blind bottom screw with niche to pack a CI that allows to evaluate the effective extraction of the air and the penetration of the sterilizing agent.

Monitoring of steam sterilization cycles is a topic of concern for nurses at MSC and the Hospital Infection Control Commission (CCIH), due to the responsibility these professionals assume in ensuring the safety and quality of sterilization processes[11].

OBJECTIVES

- To evaluate the performance of the challenge tests with CIs marketed in the monitoring of saturated steam sterilization in hospital autoclave with prevacuum system, in cycles of 134 and 121°C;
- To analyze the performance effectiveness of the challenge tests in monitoring sterilization cycles.

METHOD

The present study used as a research design the descriptive experimental study. The tests were developed on December 15th and 16th, 2016, at the Sterilized Materials Center of Hospital Estadual Bauru, managed by the Foundation for Medical and Hospital Development (FAMESP). The MSC covers an important sector of

support to the health institution, relating directly to the quality of services provided.

The equipment used in the study was the saturated steam hospital sterilizer, with an operational capacity of approximately 500 L, by Baumer®, model HI-VAC II. The qualification of operation and performance of the equipment in question was executed on November 28*th*, 2016 by JSLab Qualifications and Tests.

The tests were performed with the support of JSLab Qualifications and Tests, which used the Yokogawa DX 2030 Graphic Recorder, previously calibrated against accredited standards — Brazilian Calibration Network (BCN) with 2x24 AWG teflon/teflon "T" sensors with encapsulation fused at the tip. The objective of this support was to certify that all the items recommended in the Standard ABNT ISO 17665.1 and 17665.2 were fulfilled during the accomplishment of the tests.

Three types of products were used as challenge tests with chemical indicators: a porous package with chemical integrator in the research called Challenge package A*, by 3M® (Comply Sterigage - lot 1628800643, exp.: Oct. 2018); a porous package with a chemical emulator called Challenge package B*, by Browne® (Ref. 3870, lot 027398, exp.: 04-01-2017); and a reusable helix device with a chemical emulator called Challenge package C*, of the brand Browne®(Ref. 3779, lot 028074, exp.: 09-2018).

The temperatures chosen by the study were sterilization cycles of 134 and 121°C, parameters used in the routine of MSC sterilization. For each temperature, interruptions during the cycles in certain phases were observed, described in Table 1.

The assays were performed with the autoclave loaded and, for simulation of the load, 12 packages of surgical lay were used (Figure 1). Each package consisted of 6 units of single cotton fields, measuring 1.60 m x 1.60 m, packed in double sheets of SMS (non-woven) and zebra tape. In addition to each package, sensors were positioned for analysis during the tests of the behavior of the temperature in the inner chamber.

As an initial test of the equipment, a Bowie and Dick cycle was carried out in the empty autoclave, with a ready-to-use disposable package, with a sheet printed in sterilization sensitive ink and positioned on the drain.

After the accepted result of the Bowie and Dick cycle, the challenge tests were placed on all cycles, being positioned next to the load, on the bottom shelf, next to the loading door. At each interruption, the challenge tests were taken out and the reading was performed. New tests were placed, starting the next cycle, following the pre-established interruption times.

The cycles were monitored with 12 thermocouples positioned near the load, aiming to determine the temperature distribution in the inner chamber and to follow the evolution of the results of chemical indicators in the challenge tests, according to the time of exposure and the interruption of the cycles observed in Table 1.

RESULTS

Table 2 shows the evolution of the CIs type A of the challenge package A*, the CIs type 6 of the challenge package B* and the CIs type 6 of the helix device C*.

Table 1. Sterilization cycles of 134ºC and 121ºC and the phases of interruption.

Temperature	Cycle interruption	Cycle interruption phase
134ºC (7 minutes)	A	1st pulse
	B	2nd pulse
	C	3rd pulse
	D	Beginning of the heating ramp
	E	Beginning of sterilization
	F	1 min of sterilization
	G	2 min of sterilization
	H	3 min of sterilization
121ºC (20 minutes)	J	1 min of sterilization
	L	4 min of sterilization
	M	8 min of sterilization
	N	12 min of sterilization
	O	16 min of sterilization
	P	20 min of sterilization

Figure 1. Autoclave loaded with tissue surgical packages.

All challenge packages were subjected to a temperature of 134°C, according to the interruption phases and the total cycle time.

Table 3 shows the evolution of the turn of the chemical indicators type 5 of the challenge package A*, of the CIs type 6 of the challenge package B* and of the CIs type 6 of the helix device C*. The challenge packages were subjected to a temperature of 121°C, according to the interruption phases and the total cycle time.

DISCUSSION

The obtained results showed some deviations regarding the performances proposed by the products.

Every CI has a declared endpoint, value at which a color change occurs. However, type 5 indicators must have 3 declared values: at 121°C, 135°C and at a temperature between these values (where the biological indicator death is reached). Type 6 indicators have only a

Table 2. Evolution of the turning of the chemical indicators submitted to the temperature of 134ºC.

134ºC			
Chemical indicators type 5 of the challenge package A*			
Cycles	**Interruptions**	**Total cycle time**	**Challenge package A***
A	1st pulse	12 min	Rejected - no migration
B	2nd pulse	18 min	Rejected - no migration
C	3rd pulse	25 min	Rejected - 11% of migration
D	Beginning of the heating ramp	29 min	Rejected - 33% of migration
E	Beginning of sterilization	32 min	Accepted – 74% of migration
F	1 min sterilization	33 min	Accepted – 81% of migration
G	2 min sterilization	33 min	Accepted – 100% of migration
H	3 min sterilization	34 min	Accepted – 100% of migration
Chemical indicators type 6 of the challenge package B*			
Cycles	**Interruptions**	**Total cycle time**	**Challenge package B***
A	1st pulse	12 min	Yellow – Rejected
B	2nd pulse	18 min	Yellow – Rejected
C	3rd pulse	25 min	Yellow – Rejected
D	Beginning of the heating ramp	29 min	Yellow – Rejected
E	Beginning of sterilization	32 min	Blue – Accepted
F	1 min sterilization	33 min	Blue – Accepted
G	2 min sterilization	33 min	Blue – Accepted
H	3 min sterilization	34 min	Blue – Accepted
Chemical indicators type 6 of the helix device C*			
Cycles	**Interruptions**	**Total cycle time**	**Helix device C***
A	1st pulse	12 min	Yellow – Rejected
B	2nd pulse	18 min	Yellow – Rejected
C	3rd pulse	25 min	Yellow – Rejected
D	Beginning of the heating ramp	29 min	Yellow – Rejected
E	Beginning of sterilization	32 min	Yellow – Rejected
F	1 min sterilization	33 min	Yellow – Rejected
G	2 min sterilization	33 min	Yellow Failed - Rejected
H	3 min sterilization	34 min	Blue – Accepted

stated value for specific cycle sterilization, depending on plateau time[12].

According to the technical justification of the chemical integrator 3M Comply, revised in 2016, the CIs type 5 integrate the lethality of the biological indicator, reacting to all critical parameters of the steam sterilization process (time, temperature and steam).

It is important to consider de 2006 American National Standard of ANSI/AAMI/ISO 11140-1, which lists the expected time/temperature end point values of the CIs with the values determined for inactivation of *Geobacillus stearothermophillus* spores, in ISO 11138. This shows that, for CIs type 5, approval (final result or end point) should occur in the estimated time from 56 seconds to 1 min and 30 seconds of the exposure phase of the cycle at 134°C. In the cycles of 121°C, approval is given between 10 min and 30 seconds and 16 min and 30 seconds[13]. In the study, the approval of CI type 5 in the cycle at 134°C was obtained at the beginning of the sterilization. In the cycle at 121°C, approval occurred after 8 minutes of the exposure phase. This is due to the fact that the performance tests were performed in a conventional hospital autoclave, considering pulse times, equipment heating and steam exhaustion. However, it is possible to make a performance evaluation between the products, since they were exposed to the same conditions of time, temperature and pressure.

It was possible to verify that the performance of the challenge package B* with CI type 6 presented performance similar to the challenge package A*.

Table 3. Evolution of the turning of the chemical indicators submitted to the temperature of 121ºC.

121°C			
Chemical indicators type 5 of the challenge package A*			
Cycles	**Interruptions**	**Total cycle time**	**Challenge package A***
J	1 min of sterilization	37 min	Rejected – 25% of migration
L	4 min of sterilization	38 min	Rejected – 33% of migration
M	8 min of sterilization	41 min	Accepted – 63% of migration
N	12 min of sterilization	48 min	Accepted – 55% of migration
O	16 min of sterilization	50 min	Accepted – 59% of migration
P	20 min of sterilization	54 min	Accepted – 100% of migration
Chemical indicators type 6 of the challenge package B*			
Cycles	**Interruptions**	**Total cycle time**	**Challenge package B***
J	1 min of sterilization	37 min	Yellow – Rejected
L	4 min of sterilization	38 min	Yellow – Rejected
M	8 min of sterilization	41 min	Blue – Accepted
N	12 min of sterilization	48 min	Blue – Accepted
O	16 min of sterilization	50 min	Blue – Accepted
P	20 min of sterilization	54 min	Blue – Accepted
Chemical indicators type 6 of the helix device C*			
Cycles	**Interruptions**	**Total cycle time**	**Helix device C***
J	1 min of sterilization	37 min	Yellow – Rejected
L	4 min of sterilization	38 min	Yellow – Rejected
M	8 min of sterilization	41 min	Yellow – Rejected
N	12 min of sterilization	48 min	Yellow Failed – Rejected
O	16 min of sterilization	50 min	Blue Failed – Rejected
P	20 min of sterilization	54 min	Blue – Accepted

By analyzing the data obtained, the CIs type 5 of the challenge package A* and the type 6 of the challenge package B* presented linear performance according to the time of exposure to the temperature, being by migration of the color in the window of the indicator or change in coloration from yellow to blue.

The helix device type C* was approved for CI type 6 after 3 minutes of the exposure phase at 134ºC, corresponding to 43% of the exposure phase. In the cycle at 121ºC, the indicator approval occurred after 20 minutes of the exposure phase, that is, 100% of the exposure phase.

CONCLUSION

The results of the tests led to the following conclusions: although the porous packages A* and B* have CIs of different types (type 5 - A* - and type 6 - B*), both presented similar results, and the difference between both products are not conclusive. The results obtained by the porous challenge tests were fully satisfactory or approved at the same time when the cycles were discontinued.

It was conclusive that the challenge packages A* and B* presented cycle approval before the sterilization phase at 134ºC, and this result is an uncertainty for decision making for the nurse responsible for the MSC.

The helix device C* with indicator type 6 showed a more efficient performance in the monitoring of cycles at 134ºC and 121ºC, resulting in acceptance of the cycle in the sterilization phase, as proposed. The monitoring of the cycle until the end of the exposure phase is decisive for guaranteeing the penetration of the steam in all the material processed and the minimum lethality expected, ensuring the sterility of the materials.

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