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Original Article

IDENTIFICAÇÃO DE DETERIORAÇÕES FÍSICAS E QUÍMICAS NOS INSTRUMENTAIS CIRÚRGICOS APÓS REPROCESSAMENTOS

IDENTIFICATION OF PHYSICAL AND CHEMICAL DETERIORATION IN SURGICAL INSTRUMENTS AFTER REPROCESSING

IDENTIFICACIÓN DE DETERIORACIONES FÍSICAS Y QUÍMICAS EN INSTRUMENTOS QUIRÚRGICOS DESPUÉS DEL REPROCESAMIENTO

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RESUMO

Objetivo: identificar as deteriorações físicas e químicas apresentadas nos instrumentais cirúrgicos após reprocessamentos. **Método:** estudo transversal e quantitativo. Foram analisados 552 instrumentais cirúrgicos, com uso de lupa de aumento de 10 vezes e classificados como deteriorações físicas e químicas **Resultados:** todos os instrumentais cirúrgicos avaliados apresentaram algum tipo de alteração. Dessas, o maior percentual de danos foi encontrado da seguinte forma: 440 (79,71%) instrumentais cirúrgicos apresentaram manchas; 349 (63,0%) apresentaram perda do filme protetor; 265 (48,07%) apresentaram riscos; 253 (45,83%) apresentaram corrosão. **Conclusão:** por meio deste estudo foi possível a criação de indicadores de avaliação de qualidade dos instrumentais cirúrgicos, levando a instituição a criar novos espaços de atuação do enfermeiro e aumento de segurança nas cirurgias.

Descritores: Centros cirúrgicos; Recursos materiais em saúde; Esterilização; Enfermagem.

ABSTRACT:

Objective: to identify the physical and chemical deterioration present in surgical instruments after reprocessing. **Method:** cross-sectional and quantitative study. A total of 552 surgical instruments were analyzed using a 10 X magnifying glass and classified as to physical and chemical deterioration. **Results:** all the evaluated surgical instruments showed some type of alteration. Of these, the highest percentage of damages found were as follows: 440 (79.71%) surgical instruments presented spots; 349 (63.0%) presented loss of protective film; 265 (48.07%) presented risks; 253 (45.83%) presented corrosion. **Conclusion:** through this study, it was possible to create indicators for the quality evaluation of surgical instruments, leading the institution to create new spaces for nurses to perform and increase safety in surgeries**.**

Keywords: Surgical Centers; Material Resources in Health; Sterilization; Nursing.

RESUMEN:

Objetivo: Determinar los deterioros físicos y químicos presentados en los instrumentos quirúrgicos después de los reprocesamientos. **Método:** estudio transversal y cuantitativo. Un total de 552 instrumentos quirúrgicos fueron analizados utilizando una lupa 10 veces y clasificados como deterioro físico y químico. **Resultados:** todos los instrumentos quirúrgicos evaluados mostraron algún tipo de alteración. De estos, el mayor porcentaje de daños se encontró de la siguiente manera: 440 (79,71%) instrumentos quirúrgicos mostraron manchas; 349 (63,0%) presentaron pérdida de película protectora; 265 (48,07%) presentaron riesgos; 253 (45,83%) presentaron corrosión. **Conclusión:** A través de este estudio fue posible crear indicadores para la evaluación de la calidad de los instrumentos quirúrgicos, llevando a la institución a crear nuevos espacios para el desempeño de las enfermeras y aumentar la seguridad en las cirugías.

Descriptores: Centros quirúrgicos; Recursos materiales en salud; Esterilización; Enfermería.

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INTRODUCTION

The increase in the number of surgeries has been possible due to an extraordinary technological advance that brought considerable benefits to patients[1-2]. Inadequate use of surgical instruments, however, such as malfunction and loss of integrity, safety and performance due to repeated reuse leads to the occurrence of undesirable adverse events in patients[3].

A medical error-related death rate of one in 270 cases (0.4%), of which 65.0% were considered preventable, in a six-month period was found in a surgical center in the United States. The surgical environment is currently considered highly unsafe, with an estimated adverse event rate of 1 for every 10,000 surgeries[4].

In Brazil, the Ministry of Health published in 2009 a manual entitled "Safe Surgeries Save Lives" with the main objective of stimulating hospitals to adopt a standardized checklist prepared by specialists to assist surgical teams in reducing errors and damages to patients[5]. Although the global challenge of "Safe Surgeries Save Lives" was launched eight years ago, much is still necessary for the incorporation of good practices in surgical centers, especially with regard to the maintenance of physical and chemical conditions of surgical instruments.

Properly functioning surgical equipment and instruments are among the patient safety requirements during interventions[2,5]. Deterioration of surgical instruments such as loss of integrity and functionality may lead to increased number of adverse events. This can be avoided by investing in the design of the devices, monitoring them throughout their lifetime, and training users[2-4].

The monitoring of the lifetime of surgical instruments requires the evaluation of their chemical and physical properties after repeated reprocessing[2,6]. Such reprocessing occurs most of the times without any follow-up regarding specific validation methods that prove the presence of signs of chemical and physical deterioration to indicate the risk of reuse for patients. Due to the difficulty of specific validation methods and tests, manufacturers of reusable surgical instruments should provide validated information on the useful life of materials such as dismantling, lubrication, cleaning, disinfection and sterilization[2-4]. For this, the reprocessing steps should be carried out in an adequate manner. For example, during cleaning, the residues of organic matter or oils, drugs and enzymatic solutions may promote corrosion points and consequently reduce the useful life of the instruments[4- 7].

Studies have shown that after repeated processing, the presence of scratches, cracks and corrosion facilitate the adhesion and adsorption of several types of gram positive and negative bacteria[8-12]. Consequently, a permanent biofilm adheres to the surface of materials, impairing their reuse[11-12]. Among the most common microorganisms with capacity for biofilm formation, especially in the lumens of reprocessed materials, are *Staphylococcus aureus, Staphylococcus epidermidis, Pseudomonas aeruginosa* and *Candida spp*[11-12]. These bacteria are the ones that most often adhere to medical materials and devices in hospitals that lose their physical and chemical properties after several reprocessing cycles[12].

Furthermore, water quality is very important to prolong the life of surgical instruments, as well as to minimize risks to patients[7-8]. Water containing mineral salts can damage them and cause stains, rust and corrosion during sterilization. The quality of steam generated by autoclaves is affected by the quality of water[3-4]. Pretreatment of water such as demineralization may eliminate the possibility of residues in surgical instruments during sterilization.

It should be noted that, in addition to the inspection and validation of the reprocessing stages, some instruments have different resistance to corrosion, mechanical properties such as deformation, tension or traction that may lead to misalignment, loss of sharpness and damaged handling, impairing their reuse in surgeries[4]. Surgical scissors, for example, pass through physical deterioration over the course of various reprocessing cycles, losing the functionality of serrations and blades that cut tissues as they are opened and closed[3-4].

The durability of surgical instruments depends on the following parameters for evaluation of physical and chemical validation tests: presence of abrasive deterioration that affects the cutting edges and deterioration by fatigue and corrosion[4-6].

Such loss of functionality jeopardizes quality, especially of arthroscopic and laparoscopic surgical procedures[13]. Organization

of the instrumental boxes also influences loss of integrity and functionality. The instruments must be carefully, smoothly and individually handled or kept in small sets in order to avoid possible damages caused by entanglement and misalignment[4,8-13].

Therefore, even instruments that can be reprocessed should not be reused if their adequate physical and mechanical maintenance standards are not guaranteed and their chemical characteristics such as absence of corrosion, staining, *pitting* and porosity, are not preserved[3-4,13]. In view of the above, the objective of this study was to identify physical and chemical deteriorations present in surgical instruments after reprocessing.

METHOD

A cross-sectional and quantitative study carried out from August 2015 to July 2016 with surgical instruments at the Material and Sterilization Center (MSC) of a philanthropic teaching hospital located in the countryside of Minas Gerais.

A protocol based on the RDC of March 15, 2012 (Ministry of Health), was developed and applied[14]. The RDC 15/2012 established the requirements for good practice in processing of health products, which includes evaluating the material after different reprocessing and, if necessary, validating it to ensure its adequate reuse[14]. In the present study, quality monitoring of products was performed after processing and included a systematic and documented evaluation of the material after different processing steps[14].

Recommendations of the Guidelines of the Brazilian Association and Nurses of Surgical Center, Anesthetic Recovery and Material and Sterilization Center (SOBECC) were also included in this study[15]. In this research, we followed the recommendations of *Performance* evaluation and maintenance of surgical equipments[15].

The Quinelato® (Rio Claro, São Paulo) and Straumann® (Basel, Switzerland) manufacturers' manuals were also used in the study[16-17]. These manuals aided the evaluation of physical and chemical deterioration of materials that were included in the study. As the present research was performed with the unaided eye, without microscopy equipment, these manuals clarified concepts of deterioration that allowed differentiating different types of wear and corrosion in the materials.

Chemical and physical deterioration in surgical instruments were classified into[2,18-19]: 1) *chemical deterioration*: those cases caused by corrosion, pitting, stains, porosity and loss of protective film. Such deterioration is due to the use of cleaning products, disinfectants and sterilization after repeated reprocessing cycles; 2) *physical deterioration*: those cases of mechanical and structural wear such as presence of damaged edges, crushed ends, a hard rack, lack of sharpness, scratches, cracks, loose screws, and misalignment[2,18-19].

Data collection took place after knowing the work process of the MSC and presenting the proposal to the multiprofessional team and its impacts to the service. Surgical instruments were inspected after cleaning and disinfection using a 10X magnifying glass. A form listing the types of surgical instruments visualized in different boxes prepared for sterilization was filled out. Physical and chemical deteriorations were noted for each type of instrument. Data were recorded and analyzed using descriptive statistics in the Excel® *for Windows* software.

RESULTS AND DISCUSSION

Analysis was performed in 37 (62.7%) out of a total of 59 surgical boxes registered in the control book of the sector. Boxes with orthopedics, dentistry, gynecology, urology and ophthalmology instruments were carefully inspected, with the use of a 10X magnifying glass. In total, 552 surgical instruments were evaluated, all of which presented at least one or more chemical and/or physical damages, as shown in Table 1.

Table 1 - Physical and chemical deterioration in surgical instruments after repeated reprocessing. Diamantina, Minas Gerais, Brazil, 2016.

Physical deterioration	(N)	(%)	Chemical deterioration	(N)	(%)
Scratches	265	48.00%	Stains	439	79.71%
Damaged edges	25	4.53%	Loss of protective film	347	63.00%
Hard rack	13	2.36%	Corrosion	252	45.83%
Crushed ends	7	1.27%	Pitting	205	37.31%
Lack of sharpness	10	1.09%	Porosity	24	4.35%
Misalignment	3	0.56%			
Cracks	1	0.18%			
Loose screws	1	0.18%			

Source: prepared by the authors.

One of the factors involved in the non-occurrence of adverse events due to deterioration of surgical instruments is the quality and durability of the surgical instruments[6,17-20]. The occurrence of failures due to the loss of integrity and functionality of surgical instruments, could lead to both problems to the surgical team due to a possible cancellation of the surgery, and clinical consequences to the patient due to breaks, contact of tissues with toxic residues and even surgical site infection[2,6-7].

Surgical site infection may occur due to the presence of spots, scratches, cracks and corrosion as shown in Table 1. Such deteriorations lead to pathogen adherence and transmission through contaminated surgical instruments[3,7-8]. Moreover, after repeated reprocessing, chemical and physical deterioration of the material contributes to the contamination by endotoxins and formation of biofilms[3,7].

The highest percentage of chemical deterioration was related to stains, 79.71%. Stains may appear over time, after various reprocessing cycles, due to the accumulation of chemical contaminants from cleaning and disinfection products, water ions such as chlorine, iron, copper and manganese, and due to the steam sterilization process[3,9,13].

In the present study, surgical instruments were sterilized in steam autoclave. However, the autoclaves are old-fashioned models and may not be appropriate to provide adequate vapor pressure and temperature to ensure chemical and physical quality of the instruments after repeated reprocessing[2,7-9]. Moreover, one of the disadvantages of steam autoclaving is its ability to damage materials, leave the material wet and exposed to the risk of rust and corrosion[17-20].

In view of these results, it is important to highlight that routine maintenance of the sterilization equipment of a MSC is part of the monitoring of the process with the engineering or specific laboratories that can validate the reuse of surgical instruments[9,10]. Thus, indiscriminate frequency of reuse could be avoided without monitoring and protocols not validated by scientific evidence.

According to the *Food and Drug Administration* (FDA), visual inspection helps to identify the integrity of the device with regard to unacceptable deterioration such as corrosion, discoloration, scratches and cracking[4]. Despite the presence of such types of deterioration, considered to make instruments inadequate for reprocessing, they are still continuously reused in several types of surgeries.

Loss of protective film was the second highest index, with 63.00% of occurrence in the instruments evaluated. The protective film of stainless steel is generally made of chromium[17-20]. Steels are considered stainless when their chromium content is greater than 11.0%[19-20]. Chromium is responsible for the formation of a protective surface film called passive film, and is called so because it reduces the rate of corrosion[17-20]. Over time, however, cleaning agents, disinfectants and the steam sterilization process contribute to the deterioration of the coatings that protect the material from physical and chemical damages[3,7-9].

There are some orthopedic instruments, for example, which are made of titanium, which releases ionic residue over time in the adjacent tissue, affecting the stability of the material and producing failures of mechanical functionality[1,9,17-20]. Surfaces devoid of metal

coatings are susceptible to corrosion and exposed to dissolution of ions and long-term complications for patients such as release of toxic residues into tissues and organs due to the loss of instrumental integrity[18-20].

The control of crystallinity, composition, corrosion resistance and porosity of surgical instruments after several reprocessing cycles is still a knowledge gap[1,3-9]. Degradation of instrument coatings results in the accumulation of metallic ions in adjacent tissues that cause inflammation in patients undergoing surgeries.

Corrosion analysis of these coatings by chemical techniques is necessary to know the long-term stability of surgical instruments[1,4]. Corrosion appeared in 45.80% of evaluated instruments. One of the factors that may favor corrosion is the autoclave temperature, which should reach a maximum of 134° C[1,3-4]. If the autoclave is not calibrated, the predetermined temperature can be exceeded, significantly damaging the instrument's corrosion resistance[7-8].

Improper instrument maintenance can also result in localized corrosion[3-4,7]. This is the case of repairing welds made by non-qualified personnel. Welding processes performed by unqualified personnel result in heating well above 134°C[3-4,7]. It should be noted that sterilization cycles for surgical materials should generally occur in a cycle between 121^0C to 132^0C; however, depending on the type of material, intermediate values must be validated to avoid material deterioration[4].

Presence of roughness and of micro-cracks in the instruments may occur due to corrosion. The appearance of micro-cracks induces the formation of cracks which, in turn, increase the surface for oxidation and promote initial mechanisms of deterioration[2,13-15]. Roughness is understood as the set of diffuse irregularities like recesses and protrusions, or wavy and grainy asperity[2].

An experimental study simulated different numbers of reprocessing cycles to evaluate the presence of roughness and adhesion of bacteria in polymeric materials[10]. It was found that, after three reprocessing cycles, the surface became increasingly rough and with adhering bacteria, forming biofilms that remain after the sterilization process[10].

Another study evaluated microbiological aspects of tracheostomy tubes after different numbers of reprocessing performed in a German hospital[11]. The microbial concentration by *Staphylococcus aureus* and *Pseudomonas aeruginos*[11] inside the tubes was high. This fact is probably due to inefficient cleaning and a prior presence of a biofilm inside the tubes, verified by means of the Scanning Electron Microscopy[11].

Presence of chlorine in the instruments can lead to a type of corrosion called *pites* or *pitting*, which was identified in 37.30% of the instruments. This type of corrosion develops in the long term. Therefore, the shorter the exposure time to chlorine, the lower is the probability of appearance of this type of corrosion[4,7,9]. It should be noted that in both manual and automated washing processes, rinse temperature should not exceed 60°C[1,3]. Very high temperatures intensify corrosive processes, reducing the useful life of the surgical instruments[3,17].

As for physical deterioration such as scratches or small cracks, the incidence was 48.00% of the instruments. To avoid such damage, it is suggested that the instruments be carefully handled at all processing steps to avoid collisions, falls and contact with other sharpened materials, for example. It is also suggested that to avoid handling more than one box simultaneously and that instruments be separated by weight and fragility. The larger and heavier ones should in the bottom of the box and the more delicate and with a design of difficult handling should be on top[3-4,7].

One study evaluated the thermal and physical quality of electrosurgical pencils after different numbers of reprocessing cycles from an Italian hospital[9]. After Scanning Electron Microscopy examination, a great amount of superficial scratches and brownish residues was verified, probably due to corrosion[9]. Moreover, some pencils had fabric fibers, possibly of gauze used during manual cleaning[9]. Another interesting aspect of this study was that the presence of pitting in reprocessed surgical instruments.

In this context, it is essential to identify suitable validation tests for each type of material in order to monitor critical characteristics of the devices and to point out the quality of the material for reuse.

It should be emphasized that non-disposable surgical instruments are objects of preventive and corrective maintenance[3-4,7] after processing. Such maintenance should be performed reliably to promptly diagnose possible instrument damage, extend its useful life, and provide adequate reuse in patients.

The appearance of physical and chemical changes in the instruments evaluated may result in adverse events during patient care. According to the World Health Organization (WHO), an incident is defined as an avoidable event or circumstance arising from care, not associated with the underlying disease[6]. Incidents are classified as an "harmless incidents" when the event affect the patient but does not result in harm, but which constitutes a risk for the patient, or adverse events that necessarily result in harm to the patient[6].

According to the FDA, if the integrity and functionality of surgical instruments cannot be demonstrated and documented as safe for patients, the material cannot be reused[4]. In 2015, the FDA published a guideline with recommendations on scientific validation of reprocessing methods of medical equipment[4]. Reprocessed surgical material is understood as those which underwent cleaning, disinfection and sterilization, intended to be reused only by a single patient and intended to be reprocessed between each use.

The results of this study will contribute to the creation of indicators for evaluation of the quality of surgical instruments, and also favor the creation of maintenance protocols, without which it is impossible to carefully evaluate the quality of materials, restructuring and standardizing of services, and systematic surveillance of sterilization and preservation processes of surgical instruments. For the effectiveness of this process, it is fundamental that nurses of Surgical Centers keep updated and in constant scientific and practical improvement on the effective and recommended actions of the MSC.

CONCLUSION

The identification of physical and chemical deterioration was a signaling element to indicate the possibility of the emergence of adverse events during any stage of surgical processes. It is important that the MSCs of Health Care Institutions have governance to ensure the legitimacy of reprocessing actions that not only includes inspection, cleaning, preparation, packaging, labeling, disinfection or sterilization, but also the realization of biological and chemical tests, residual analysis of sterilizing agents, and functionality and integrity of materials. It is, thus, essential to ensure that each surgical instrument, for example, be reused without exposing patients to the risk of adverse events.

An important fact is that this study contributed to the creation of the Safety Center of the researched Health Institution and to the development of scientific and technological projects related to the maintenance of surgical instruments. This project was the starting point of partnerships with laboratories with scanning electron microscopy to determine how many reprocessing cycles materials can undergo before reuse. In addition, physical and chemical tests such as corrosion resistance and sterilization tests to detect the life cycle of stainless steel surgical material after repeated reprocessing were recommended. After this study, the selection and separation of damaged materials and forwarding for repair and maintenance were strictly monitored. Therefore, instruments with corrosion, scratches, *pitting* or deterioration visible to the naked eye were no longer reused.

Finally, this study may also contribute to raise awareness among institutions and health professionals about health surveillance, which has the role of monitoring the compliance with its regulations and eliminating, reducing or preventing health risks arising from surgical instruments.

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