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Central sterile services department: screening of automated cleaning in liposuction cannulae

Centro de materiais e esterilização: rastreamento da limpeza automatizada nas cânulas de lipoaspiração

Central de material y esterilización: seguimento de limpeza automatizado en las cánulas de liposucción

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ABSTRACT

Objective: To evaluate the effectiveness of automated cleaning of 4 mm liposuction cannulas using ultrasonic washer machine, screening for dirt using a cannulate microscope device and the screening of viable strains of *Staphylococcus aureus*, with microbiological analysis.
Method: Experimental study with 14 units of 4 mm liposuction cannulas performed at the Central Sterile Services Department and at the Microbiology Laboratory of a Hospital Complex, located in Porto Alegre, RS, Brazil, from October 2018 to April 2019.
Results: Of the 14 liposuction cannulas that constituted the sample, 42.9% remained dirty despite automated cleaning, and all of them showed recovery of viable microrganisms in the microbiological laboratory.
Conclusion: The study showed that it is not possible to ensure the cleaning efficacy of automated cleaning of 4 mm liposuction cannulas, especially due to the conformation of the material with internal spaces with accumulation of dirt.
Keywords: Surgical instruments. Sterilization. Perioperative nursing.

RESUMO

Objetivo: Avaliar a eficácia da limpeza automatizada realizada com lavadora ultrassônica de cânulas de aspiração de 4 mm, por meio do rastreamento de sujidade interna feito com aparelho de microscopia para canulados e o rastreamento de cepas viáveis de *Staphylococcus aureus*, por análise microbiológica.
Métodos: Estudo experimental realizado com 14 cânulas de lipoaspiração de 4 mm em um Centro de Material e Esterilização e no laboratório de microbiologia de um hospital de Porto Alegre, Brasil, no período de outubro de 2018 a abril de 2019.
Resultados: Das 14 cânulas de lipoaspiração que constituíram a amostra,42,9% permaneceram com sujidade mesmo após a limpeza automatizada e todas apresentaram recuperação de microrganismos viáveis nos testes do laboratório de microbiologia.
Conclusão: O estudo mostrou não ser possível garantir a eficácia da limpeza automatizada nas cânulas de lipoaspiração de 4 mm, em especial devido à conformação do material com locais onde acumula sujidade.
Palavras-chave: Instrumentos cirúrgicos. Esterilização. Enfermagem perioperatória.

RESUMEN

Objetivo: Evaluar la efectividad de la limpieza automatizada mediante la lavadora ultrasónica de las cánulas de liposucción de 4 mm, mediante el rastreo de la suciedad interna, utilizando el dispositivo de microscopía para canulados y el cribado de cepas viables de *Stphylococcus aureus*, mediante análisis microbiológico.
Método: Estudio experimental realizado con 14 cánulas de liposucción de 4 mm en un Centro de Material y Esterilización y en el laboratorio de microbiología de un hospital de Porto Alegre, Brasil, de octubre de 2018 a abril de 2019.
Resultados: De 14 cánulas de liposucción que constituyeron la muestra, el 42,9% permaneció sucio, incluso después de la limpieza automática y todos mostraron recuperación de micoorganismos viables en el laboratorio de mocrobiogía .
Conclusión: El estudio mostró que no es posible garantizar la efectividad de la limpieza automática en las cánulas de liposucción de 4 mm, especialmente por la conformación del material con lugares donde se acumula suciedad.
Palabras clave: Instrumentos quirúrgicos. Esterilización. Enfermería perioperatoria.

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INTRODUCTION

The Material and Sterilization Center (CME) plays a relevant role in quality care actions in a hospital. The growing importance, specificity and recognition of the CME were established with the understanding of the work processes, as well as the complexity of the actions developed[1].

This complexity is directly related to the set of actions developed by the CME, which include: receipt, cleaning, inspection, disinfection, preparation of materials, sterilization, storage and distribution of materials throughout the hospital[1–4].

The evolution of processes with the use of increasingly complex and sophisticated surgical instruments makes activities difficult, requiring frequent updating. It is noteworthy that the result of the work developed at the CME is directly related to the safety of patient care[1–7]. Therefore, the greatest concern of professionals working at the CME is to provide safe materials for use in the most diverse areas of the hospital[8].

Moreover, the same surgical instrument can be used several times during the year by numerous patients. However, if not properly processed, this material can contaminate hundreds of patients resulting in surgical site infections[5–6].

Surgical instruments or devices were classified, more than 50 years ago by Spaulding, into critical, semi-critical and non-critical[9]. The critical ones are those that come into contact with the patient's sterile tissues and liquids, and therefore must be sterilized[7]. Sterilization presupposes a better safety margin for processed materials, as it is a process that aims to eliminate pathogenic microorganisms and spores. However, health products that are not properly sanitized, with total removal of organic or inorganic matter from their surface, will have an inefficient sterilization process[1–2,10–11].

Therefore, the process of cleaning surgical instruments is essential to ensure sterilization[12]. This should be done on the entire surface of the material, including recesses, joints and lumens (often narrow), in order to avoid the formation of biofilm and reduce the microbial load[7]. The accumulation of waste in the reprocessed material generates the biofilm; this film prevents penetration of the sterilizing agent into the material, resulting in reprocessing failure. Thus, cleaning is the most critical step in the reprocessing of materials and where more errors occur, such as: not filling the lumens and not promoting friction on the surface of the material[1–2,7,9].

Naturally, when presenting cleaning as the most important process in the reprocessing of health products, one must insist on the search for evidence that assures the effectiveness of the process[1–2,6–7]. In this context, the research problem to be investigated is: what is the effectiveness of automated cleaning performed by means of an ultrasonic washing machine in 4 mm suction cannulas? The objective was to evaluate the effectiveness of automated cleaning performed with an ultrasonic washer of 4 mm aspiration cannulas, by screening internal dirt using a cannulate microscope device and by screening viable strains of *Staphylococcus aureus* , using microbiological analysis.

METHODS

The study was approved by the Research Ethics Committee (CEP) of the hospital where it was carried out under Protocol no CAAE 08905119.0.0000.5335.

Experimental laboratory study, guided by the SQUIRE 2.0 tool[13], developed at the Material and Sterilization Center and at the microbiology laboratory of a hospital in the City of Porto Alegre, Rio Grande do Sul, Brazil in partnership with a Federal University, from October 2018 to April 2019.

The study population consisted of 22 units of 4 mm liposuction cannulas available at the service during the data collection period. Inclusion criteria were all 4 mm liposuction cannulas made available by the CME. The exclusion criteria adopted were: cannulas that were no longer in use by the service and with apparent dirt impregnated, with possible contamination and without the possibility of descaling and/or without the possibility of internal inspection due to the caliber of the cannula. Therefore, after application of the inclusion and exclusion criteria, the sample consisted of 14 units of 4 mm liposuction cannulas, which were used in the study.

Study Protocol

Data collection and evaluation of automated cleaning were performed in nine steps, namely: (1) Selection and Identification of Cannulas: 22 units of 4 mm liposuction cannulas, as an intentional sample available for the study. Each cannula was marked with silicone rings, with different color patterns for their identification. Identification was necessary for data analysis. (2) Cleaning: the second step was the cleaning process of the 4 mm liposuction cannulas, with the retro-flow Caviwave® ultrasonic washer and 3M® multi-enzyme cleaner, rinsing with purified water and drying, according to protocols and routines of the CME of that hospital complex. (3) External and internal visual inspection: After cleaning the cannulas, an internal inspection was carried out with the aid of a device suitable for cannulas (Stericam®) with a flexible fiber optic cables with a diameter of 2.3 mm and a length of 110 cm, and the images were recorded for the identification of apparent dirt, organic or inorganic

matter and material wear/damage, such as oxidation. At this stage, the exclusion criteria were applied, and a sample of 14 cannulas was established.

After the number of samples was established, the experimental stage of the protocol began. (4) Processing: the cannulas went through the entire cleaning process in the ultrasonic washer, drying, inspection, individual packaging in medical grade paper and the sterilization process by steam autoclave, in compliance with the protocols and routines of the institution. (5) *Staphylococcus aureus* ATCC 25923 and Soil Test® impregnation: the sterilized cannulas were sent to the microbiology laboratory, transported in rigid and hermetically sealed plastic packaging for impregnation of the *Staphylococcus aureus* ATCC 25923 bacteria strains (the choice of this microorganism was arbitrary, due to the accessibility of the laboratory and these strains), and for the Soil Test™ (soil test made up of a powder mixture that simulates the characteristics of blood and other organic matter). This procedure was performed with aseptic technique and in a biosafety cabinet.

The validation process of the bacterial load inoculation method, followed by count of the number of microorganisms removed from the product occurred according to ISO 11737-1:2018: Sterilization of Health care products, microbiological methods – part 1: determination of population of microorganisms on products. Inoculum of 3 mL of 5.0 x 106 of the same strain of *Staphylococcus aureus* described in association with the Soil Test™ were impregnated. (6) Drying: the cannulas were dried in the microbiology laboratory for 24 hours to ensure total adherence to the surface of the instrument as well as the Soil Test™.

Finally, the final steps of the method were carried out, which are microbiological evaluation and evaluation of the effectiveness of automated washing. (7) Wash in Trypticase Soy Broth Medium (TSB) and duplicate cultivation on Standard Plate Count Agar (PCA): after the drying period, 12 consecutive washes were performed in each cannula, using 10 mL of TSB culture broth; each sample obtained and identified was placed on standard counting agar plates (PCA) for microorganisms, using the surface inoculation technique (Spread plate method) and incubated for 24 hours at a temperature of 32.5 ± 2, 5ºC. (8) Post impregnation cleaning: The automated cleaning process was performed with the ultrasonic washer in the CME, using the same standard operating procedure mentioned above, after impregnation of the tests, in order to achieve the objective of evaluating the effectiveness of the washing. (9) Inspection with microscopy device suitable for cannulas: last stage of the method where the internal visual inspection of the cannulas took place, with the microscope for cannulas (Stericam®) in order to evaluate the effectiveness of cleaning the dirt simulated by the Soil Test™.

Data were inserted in a Microsoft Excel® spreadsheet, analyzed descriptively, according to findings and frequencies, and presented in tables.

RESULTS

In the stage of identification of the cannulas, the CME processed the 4 mm cannulas available for the research, providing biosecurity for the process, and to ensure random selection, all cannulas were packed in medical grade paper for sterilization (package with paper on one side and polyester and polypropylene film on the other side, with a chemical indicator for the process used, and distinction between them not possible.

The research began with 22 units of 4 mm liposuction cannulas, made available by the CME, and they were duly identified in the microbiology laboratory in a controlled environment, with different color patterns.

In the visual inspection stage, the study exclusion criteria were applied, that is, those cannulas that showed wear/oxidation and/or dirt without the possibility of descaling (Figure 1) were excluded from the study, since cannulas known to be dirty are a bias for data analysis. Therefore, eight liposuction cannulas were excluded from the study, and the total sample consisted of 14 cannulas.

In this context, the cannulas used in the present study were submitted to the entire methodology proposed, and the following results were obtained: six cannulas had dirt positive for microbial growth in internal inspection, as follows: cannulas number 3,7,8,10, 17 and 22, which was a failure in the cleaning process of 42.9% of the items, regarding the presence of dirt, and it should be noted that all cannulas were positive for the presence of microorganisms (Chart 1). Thus, the method of washing cannulas with TSB culture medium was used (which is enriched for the growth of microorganisms, in case they were still inside the cannulas). For the procedure, 12 consecutive washes were performed in each cannula, using 10mL of TSB culture broth. Each sample obtained and identified was placed on standard counting agar plates for microorganisms, using the spread plate technique, and incubated for 24 hours at a temperature of 32.5 ±2.5ºC. In all cultures, the growth of microorganisms was the same as that of the inoculum. Figure 2 shows the visualization of the internal microscopy of one of the cannulas to evaluate the presence of dirt, after automated cleaning.

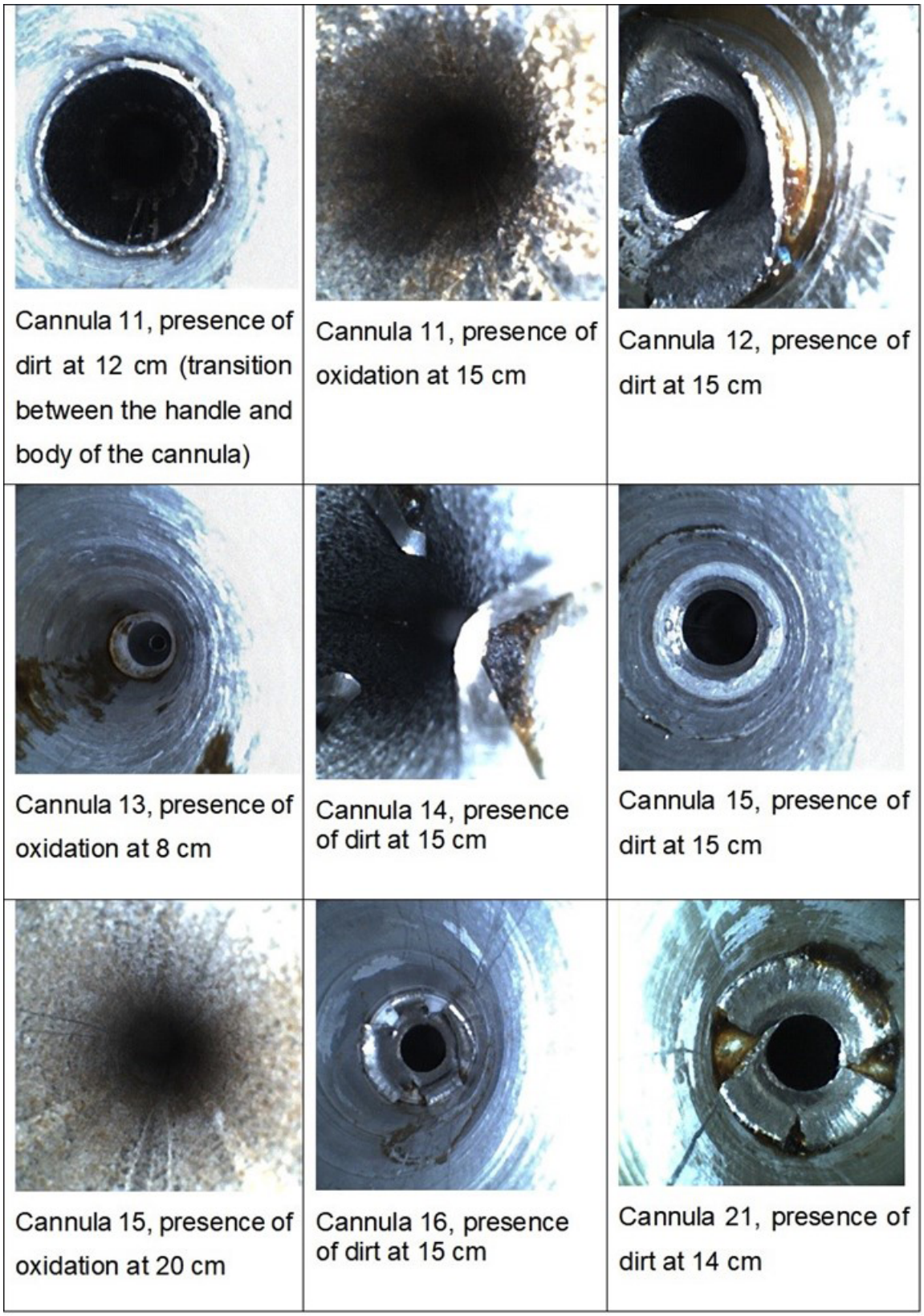

Figure 1 – Record of the presence of dirt and/or oxidation on the cannulas. Porto Alegre, Rio Grande do Sul, Brazil, 2020
Source: Research data, 2019.

Cannula	Growth of Culture	Internal Inspection	Crossing
2	Yes	Negative	Microorganism
3	Yes	Positive	Microorganism more presence of dirt
4	Yes	Negative	Microorganism
5	Yes	Negative	Microorganism
6	Yes	Negative	Microorganism
7	Yes	Positive	Microorganism more presence of dirt
8	Yes	Positive	Microorganism more presence of dirt
9	Yes	Negative	Microorganism
10	Yes	Positive	Microorganism more presence of dirt
17	Yes	Positive	Microorganism more presence of dirt
18	Yes	Negative	Microorganism
19	Yes	Negative	Microorganism
20	Yes	Positive	Microorganism more presence of dirt
22	Yes	Negative	Microorganism

Chart 1 – Results of microbiological analysis and internal inspection of 4.00mm liposuction cannulas. Porto Alegre, Rio Grande do Sul, Brazil, 2020
Source: Research data, 2019.

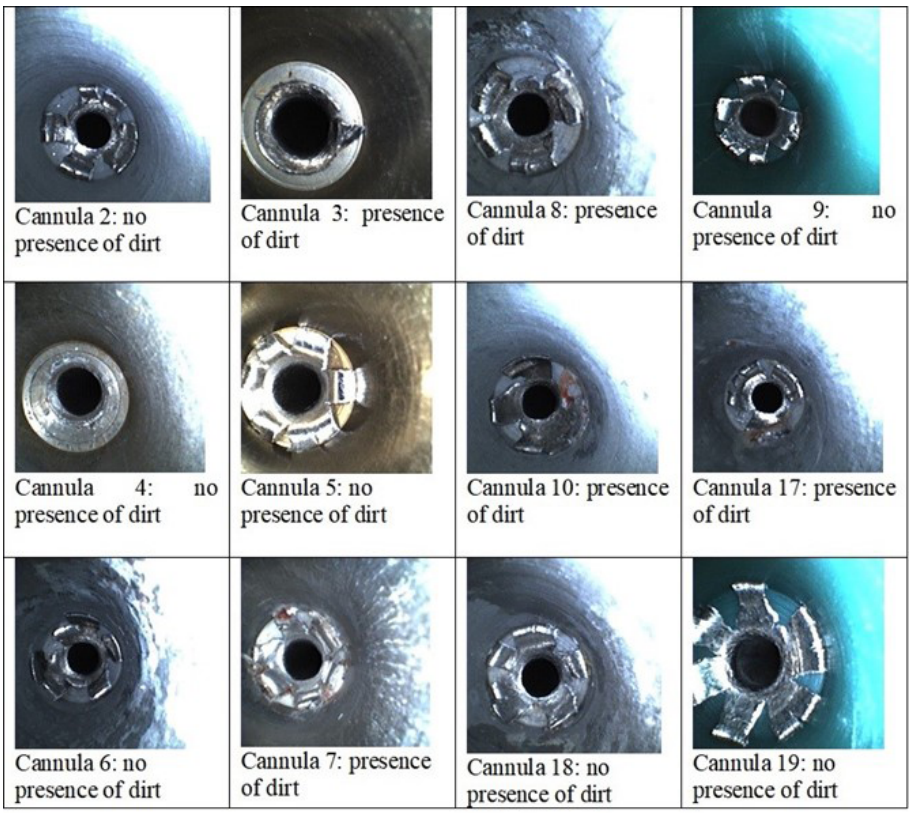

Figure 2 – Record of the internal inspection of the cannulas to evaluate the presence of dirt, after automated cleaning, evidenced by the presence of Soil Test®. Porto Alegre, Rio Grande do Sul, Brazil, 2020
Source: Research data, 2019.

DISCUSSION

In the present study, although standard cleaning procedures recommended by manuals and validated with best practices were employed, automated cleaning did not completely remove dirt from the cannulas, mostly due to their conformation.

Challenges of Product Conformation and Presence of Dirt

Liposuction cannulas have a complex conformation, which does not provide easy visualization during the cleaning process, influencing this process, since these items cannot be disassembled. In addition, as was seen in this study, the cannulas have areas with excess material or inappropriate finishing, which allow the accumulation of dirt[11].

The design and manufacture of these health products (HPs) make it impossible to completely remove the dirt. Some studies have shown that certain instruments, in fact, would not be subject to processing[14], due to their design and difficult access to internal areas.

The criticality of an effective cleaning of liposuction cannulas is also related to the type of material with which they come in contact during surgical procedures, that is, sterile tissues, blood and fat, which strongly adhere to the HPs and accumulate in areas of difficult internal access of the cannulas. Thus, corroborating the findings of the present study, the accumulation of dirt is recurrent in other studies with cannulate materials, which evaluated the markers and indicators of microorganisms in endoscopes, of complex conformation, showing ineffectiveness of reprocessing and an increased risk of infection for the patients[15–16].

Consequently, the cannulas with a positive visual inspection test for the Soil Test accumulated dirt, especially in areas with rough finish and excess material, which create favorable spaces for the fixation of organic matter and great difficulty for cleaning.

Furthermore, a study[17] aimed to investigate outbreaks of infections, involving endoscopes, shows the specific challenges of cleaning healthcare products that contain lumens: it found protein residues and biofilm formation in the channels of endoscopes, even after multiple cleaning revalidation. This emphasizes the need for implementation of a cleaning monitoring routine to prevent materials from being sent for disinfection or sterilization with the presence of organic or inorganic matter[5].

In an outpatient surgery center in the United States, more than 30% of the endoscopes used contained viable microorganisms, even after reprocessing. The research had a two-month follow-up and 17 endoscopes were evaluated[18].

The present study found that in moments of haste or urgency, the most neglected step is cleaning, putting patients at risk. Therefore, when cleaning and objective inspection are not performed, patients can be subjected to procedures with contaminated equipment/instruments[2,17].

Collaborating with these data that exposed failure in the cleaning step of medical devices, through the lack of adequate monitoring, a report that evaluated the safety of processing flexible intramedullary burs for orthopedic surgery reported that 34% of 234 events where material contamination was detected in the operating room, were related to inadequate cleaning and inspection[14]. Likewise, in the present study, dirt was associated with 42.9% of cleaning failures and the presence of microorganisms.

Viable microorganisms and presence of dirt

Another relevant concern with the data of the present study are the viable microorganisms associated with the load of organic matter. Furthermore, data show that an efficient cleaning could lead to a reduction of about 99% of the bioburden, as long as the substrate or dirt load present in the material is eliminated[2,9,19]. However, the findings showed that the cleaning procedure of 42.9% of the cannulas was not efficient and, therefore, there was organic matter associated to the inoculated microorganism (*Staphylococcus aureus*).

Furthermore, the cleaning process is very complex due to the formation of biofilm, as *Staphylococcus aureus* is one of the most relevant microorganisms for the formation of this material, which consists of multilayers that strongly adhere to the material, impairing the action of sterilizing agents[2].

Another study[19] that evaluated the microbiological load of materials with complex orthopedic conformation identified the presence of oil and biofilm even after 20 cleaning cycles. It corroborates the present findings on dirt and recovery of viable microorganisms, in which biofilm formation can occur, in addition to emphasizing the difficulty of cleaning associated to the complex conformation of the material.

Study Limitations

The limitations concern the sample size and statistical analysis, as well as the use of only one microorganism that was evaluated.

Contributions to the Area

It is believed that this study contributed to highlighting the importance of developing knowledge about the Material and Sterilization Center and about how the activities developed in this sector can directly influence patient safety.

CONCLUSION

The present study attempted to demonstrate the importance of CME and the cleaning stage and, thus, of the careful inspection of health products, especially liposuction cannulas, which have a complex conformation/design.

However, although the cleaning protocol recommended by the guidelines and all the steps proposed in the methodology were observed, in order to demonstrate the effectiveness of automated cleaning, it was not possible to guarantee the effectiveness of the process, as the presence of contamination was identified in 42.9% of the cannulas, largely due to the inner design of these items.

These findings can be considered for reviews by reprocessing committees of health products, as a single-use product and/or cleaning solutions well established in manuals provided by manufacturers, as well as alternatives for material finishing and disassembly of the parts. Moreover, alternative materials must also consider the sustainability of the processes and the consequences for the environment, as well as the financial health of healthcare organizations.

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