SAFETY ASSESSMENT OF REPROCESSING OF FLEXIBLE INTRAMEDULLARY BONE REAMERS FOR ORTHOPEDIC SURGERY

Avaliação da segurança do processamento de fresas intramedulares flexíveis para cirurgia ortopédica

Evaluación de la seguridad del procesamiento de fresas intramedulares flexibles para cirugía ortopédica

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ABSTRACT: Objectives: To assess the efficacy of a standard operational procedure to clean flexible intramedullary bone reamers, as well as the sterilization level, and to show the cytotoxicity of the residual dirtiness of a flexible reamer used in care practice. **Methods:** Flexible intramedullary bone reamers were weighed before processing, after challenge contamination and after cleaning. They were contaminated with the Soil Test™, Geobacillus stearothermophilus suspension, in the concentration of 10^6 cfu/ml, and bovine bone flour. After processing, the samples were inoculated into a culture medium and incubated for 21 days. Residual dirtiness of a flexible intramedullary bone reamer used in practice was submitted to in vitro cytotoxicity test. **Results:** Despite being sterilized, the samples indicate to accumulated dirtiness and the processing was inefficient. Residual dirtiness presented a cytotoxic effect. **Conclusion:** It is recommended that the flexible design of reamers is discontinued by the lack of safety of reprocessing.

Keywords: Nursing. Orthopedics. Sterilization.

RESUMO: Objetivos: Avaliar a eficácia de um procedimento operacional padrão para limpeza de fresas intramedulares flexíveis, bem como o alcance da esterilidade, e evidenciar a citotoxicidade da sujidade residual de uma fresa flexível utilizada na prática assistencial. **Métodos:** Fresas intramedulares flexíveis foram pesadas antes do processamento, após contaminação desafio e depois da limpeza. Elas foram contaminadas com Soil Test™, suspensão de *Geobacillus stearothermophilus*, na concentração de 10^6 UFC/mL, e farinha de osso bovino. Após processamento, as amostras foram incubadas em meio de cultura por 21 dias. A sujidade residual de uma fresa utilizada na prática foi submetida ao teste de citotoxicidade *in vitro*. **Resultados:** As amostras, embora esterilizadas, apontaram acúmulo de sujidade e o processamento foi ineficaz. A sujidade residual apresentou efeito citotóxico. **Conclusão:** Recomenda-se que o *design* flexível das fresas seja descontinuado pela insegurança no processamento.

Palavras-chave: Enfermagem. Ortopedia. Esterilização.

RESUMEN: Objetivos: Evaluar la eficacia de un procedimiento operacional estándar para limpieza de fresas intramedulares flexibles, así como el alcance de la esterilidad, y evidenciar la citotoxicidad de la suciedad residual de una fresa flexible utilizada en la práctica asistencial. **Métodos:** Fresas intramedulares flexibles fueron pesadas antes del procesamiento, tras contaminación desafío y después de la limpieza. Fueron contaminadas con Soil Test™, suspensión de Geobacillus stearothermophilus, en la concentración de 10^6 UFC/mL, y harina de hueso bovino. Tras el procesamiento, las muestras fueron incubadas en medio de cultura por 21 días. La suciedad residual de una fresa utilizada en la práctica fue sometida al test de citotoxicidad in vitro. **Resultados:** Las muestras, aunque esterilizadas, apuntaron acumulación de suciedad y el procesamiento fue ineficaz. La suciedad residual presentó efecto citotóxico. **Conclusión:** Se recomienda que el design flexible de las fresas sea descontinuado por la inseguridad en el procesamiento.

Palabras clave: Enfermería. Ortopedia. Esterilización.

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INTRODUCTION

Flexible intramedullary bone reamers are medical devices that can be reprocessed, besides being thermoresistant, with complex conformation. They present extreme cleaning difficulties. These products are constituted of stainless steel and are characterized by a shaft whose flexibility is provided by two stainless steel ribbons overlapped in a spiral shape, one spiralled clockwise and another one spiralled counter-clockwise, forming a flexible structure similar to a coil. This shaft is connected to a tip developed to ream the surface of the intramedullary canal of long bones.

The difficulty in cleaning is attributed not only to its conformation, but also to the dirtiness resulting from the surgical procedure itself, which includes blood, bone, and bone marrow. This dirtiness is spread over the shaft, and most of it is retained in the space between the two steel ribbons, especially in the extremities (with lower flexibility), making it difficult to remove it, since this space is inaccessible to the artifacts and technologies available for cleaning.

The literature about flexible intramedullary bone reamers is concentrated on functional aspects and is scarce as to the safety in cleaning and sterilization. This is a matter of concern, once the scientific literature reports the survival of microorganisms in its vegetative form in the instruments used for orthopedic surgeries after steam sterilization, due to flaws in cleaning.

In 1999, a report was published on three cases of *Staphylococcus epidermidis* septic arthritis. The authors identified dry organic matter in cannulas that would be used in orthopedic procedures[1]. In another study, published in 2009, the authors found organic matter in lumens, with positive culture for coagulase-negative *Staphylococcus*, *S. epidermidis*, and *Streptococcus mitis*[2]. In 2011, an outbreak of *Pseudomonas aeruginosa* was also associated with flaws in the reprocessing of orthopedic surgery instruments, which had residues of organic matter[3].

Besides the risks related to the infection, associated with the difficulty or the impossibility of cleaning, the toxicity of residual dirtiness contained inside the reamers has not been shown yet, and the impact of these residues in the occurrence of local and systemic inflammatory processes is not known.

On the basis of these reports, this article aims at assessing the efficiency of a standard operating procedure (SOP) for cleaning flexible intramedullary bone reamers, as well as the sterilization level, besides showing the cytotoxicity of residual dirtiness in a flexible intramedullary bone reamer used in care practice.

METHODS

This is a laboratory experimental study conducted in two stages, between 2015 and 2016, and carried out in the following laboratories: Laboratory of Microbiological Trials, in the Nursing School of *Universidade de São Paulo*, Laboratory of Microbiology in the Pathology Department of the School of Medical Sciences at *Santa-Casa de São Paulo*, and the Group of Cell Culture in *Instituto Adolfo Lutz* (São Paulo).

Stage 1: evaluation of cleaning and sterilization

Samples were flexible intramedullary bone reamers for the humerus, 27.5 mm long and with internal diameter of 0.4 mm (Tech Tools®, Brazil) (Figure 1). In this evaluation, three newly manufactured reamers were used, which had not been used in care practice. They were identified by the colors, green, blue, and red.

To evaluate the cleaning, each reamer was weighted in three moments: before each reprocessing (basal weight), after the challenge contamination, and after cleaning. So, the accumulated value was calculated, given by the difference between weight after cleaning and basal weight, using a weigh digital scale (0.01g sensitivity) (Shimadzu Corp., Japan). To simulate its care use, each sample was submitted to a challenge contamination, internally and externally, with Soil Test™,

Figure 1. Semi-rigid intramedullary orthopedic reamer (above) and flexible intramedullary reamer for humerus used as a sample in this study (below).

and *Geobacillus stearothermophilus* suspension in the concentration of 10^6 cfu/ml, containing spores.

After being contaminated with the solution, the samples were contaminated, internally and externally, with bovine bone flour (~3,5 g), simulating the bone residue at the end of a surgical procedure[4]. Contact with contaminants was maintained for 3 hours, which is the estimated time of a surgical procedure. After this period, the samples were processed according to SOP: pre-humectation in tap water for 5 minutes; brushing of the external shaft surfaces (Mack Medical®, Brazil); brushing of the external surfaces of the tip (Mack Medical®, Brazil); clearance of the lumen with a guidewire (when necessary); lumen washing with a pressure water gun (RFQ®, Germany), for 5 seconds, or until it is no longer obstructed; brushing the lumen five times (Mack Medical®, Brazil); rinsing in tap water; washing with enzymatic detergent Endozime™ Xtreme Power (Ruhof®, United States of America) in ultrasonic cleaner (Medisafe® SI Digital, United Kingdom) with cannulated instrument connections at 50ºC for 5 minutes; rinsing in tap water; complementary rinsing with purified water; drying the internal surfaces with filtered compressed air; inspection; individually wrapped in surgical grade papers/film (Amcor®, Australia); and sterilization in autoclave at 135ºC for 4 minutes (Tuttnauer®, Israel).

After sterilization, the samples were inoculated in 250-ml test tubes, with sterile tryptic soy broth medium (BD®, United States of America). This procedure was carried out with an aseptic technique, inside a biological safety cabinet. Then, the samples were incubated at 56°C for 21 days, with daily reading of the recovery of *Geobacillus stearothermophilus*.

These procedures were repeated three times to simulate three reuses of each sample. To test the validity of the results, the simulated reuses were followed-up with a negative control, that is, a new reamer without a challenge contamination, submitted to reprocessing and incubated in a sterile tryptic soy broth medium for 21 days. We also used a positive control, that is, a reamer submitted to the challenge contamination and incubated in a tryptic soy broth medium right after – both at 56ºC.

Stage 2: *in vitro* cytotoxicity test

In vitro cytotoxicity assays are methods aiming at determining the biological response of mammal *in vitro* cells, through defined biological parameters, constituting an attempt to simulate or exaggerate conditions of clinical use, in order to show toxic risk[5]. In this stage, a flexible intramedullary reamer for femur was used after eight reuses in care practice. The external steel ribbon was removed, and the dirtiness adhered to the internal ribbon was collected, aseptically, in a test tube. After this procedure, the *in vitro* cytotoxicity test of the residual was conducted, using the agar diffusion test. Triplicate analyses were carried out.

This assay used the cell line *National Collection of Type Cultures* (NCTC) clone 929 (L cell, L-929, derivative of Strain L) (American Type Culture Collection® CCL1™), registered in the collection of the Group of Cell Culture in *Instituto Adolfo Lutz*, number CCIAL020. This test used the following procedures: NCTC clone 929 cells were seeded in Petri dishes, treated for cellular cultures, measuring 60x15 mm (TPP®, Switzerland), in a concentration of 3×10^5 cells/mL and volume of 5 mL. The cultures were incubated for 48 hours at 37ºC±1ºC, in an atmosphere containing 5% of CO_2. After this period, cellular monolayers were assessed as to confluence, and the culture medium was replaced by an overlay medium composed of a twice concentrated Eagle's medium and agar (BD®, United States of America) at 1.8% with 0.01% of neutral red vital stain. In preparation[6], agar was proportionally mixed (1:1) to the Eagle's medium, both at 44°C. Cellular toxicity was observed in a microscope by the alteration of morphology or the death of cells around or under the sample; and, macroscopically, for the formation of the colorless halo around the cytotoxic material[6]. After the measurement of the extension of the colorless halo taken from the sample, the cytotoxicity was classified according to the levels of reactivity for the agar diffusion test described in ISO 10.993-5:2009 standard[5].

RESULTS

The cleaning SOP used was inefficient, as it was not able to completely remove the dirtiness of the samples. The mean difference in the weight of the samples after the reuses was of 0.30 g (Table 1).

Even though the SOP had failed, the required sterilization level was observed in all samples; therefore, no turbidity was observed in the culture medium at the end of the 21-day-incubation period. The results of the negative and positive control were in accordance with expectancies for the three simulated reuses.

Residual dirtiness obtained in the flexible intramedullary reamer for femur pointed out to a cytotoxic effect with degree 3 of biological reactivity, average of 0.31 cm of halo in the triplicates, that is, moderate cytotoxic effect.

DISCUSSION

Inefficacy of the standard operating procedure

Brazilian legislation demands that each stage of surgical instrument reprocessing be conducted using an elaborated SOP, based on updated scientific references and pertinent regulation[7]. This study used manual and automatic cleaning methods, with demonstrated efficacy, but still, the conformation of the reamers did not allow the complete removal of dirtiness.

In complex conformation instruments, the impossibility to totally remove the dirt was also observed in a study conducted with instruments used for minimally invasive surgeries, which used the contaminant ATS® (Artificial Test Soil), composed of 85.2 mg/mL of protein, 12.3 mg/mL of carbohydrates, and 4.12 mg/mL of hemoglobin. In this case, the authors obtained a reduction of 99% in contaminants after the ultrasonic cleaning of the samples[8].

The quantification of insoluble residues is a method that has been described in the literature to assess the dirtiness in the orthopedic instrument. An investigation from 2012 used the membrane filtration technique and the weighing of insoluble organic matter (clotted blood and bovine bone flour) in products with lumen for orthopedic surgeries[9]. In this study, this technique was not feasible due to the internal space between the metallic ribbons constituting the body of the reamers, which did not allow the elution of insoluble dirt; therefore, to perform residues control using the total weight of the samples was necessary.

The same study analyzed residues in orthopedic devices with lumen, which were artificially contaminated with bone cement, and observed the retention of residues after ten cycles of contamination and cleaning[9]. The authors concluded that the complexity of the design influences the retention of dirt, similarly to what was observed for flexible intramedullary reamers.

Because of the design of the flexible reamer, the SOP included several manual steps during the cleaning stage, which would require special attention from the cleaning staff. During the experiments, only the application of the cleaning stages, including drying, required approximately 15 minutes for each sample.

In the daily routine of a central sterile service department (CSSD), especially in major general hospitals, with great diversity in instruments, it would be impossible for an employee to spend 45 minutes of his or her six-hour shift in only three products. Besides cleaning, other activities are also required, like receiving, checking, separating, disassembling, and referring the products.

In most cases, SOPs are validated in laboratory conditions, without considering the dynamics of work processes or the dimension of human resources and infrastructure. Even though the products of complex conformation require more elaborated SOPs, it is necessary to observe that a very long SOP, with many manual cleaning steps, may lead to the non-adherence to all of the stages, especially at times with higher demand in the cleaning area of the CSSD.

Non-systematic observations show that the services tend to sacrifice the efficacy and favor the efficiency of processes. In other words, the high demand for production, added to the deficit in infrastructure and human resources, may lead to the suppression of important steps of product cleaning. Therefore, it is urgent that health product manufacturers prioritize not only functionality, but also the effective processing, investing in more accessible design for manual or automatic cleaning stages, such as semi-rigid reamers.

Table 1. Distribution of weight in flexible orthopedic nails after reuses in comparison to basal weight. São Paulo, 2016.

Nail	Basal weight (g)	Accumulated weight (g)			Final weight (g)	Difference (g)
		1. Reuse	2. Reuse	3. Reuse		
Red	72.58	0.28	0.31	0.18	72.88	0.30
Blue	76.17	0.31	0.30	0.23	76.52	0.35
Green	73.27	0.31	0.23	0.19	73.51	0.24
				Mean (g)		0.30

The main facilitator for the management of SOPs in the CSSD is the accessible design for cleaning. The management of SOPs by brand and type of product is required; however, in a major general hospital that works with several surgical specialties, there would be an excessive number of SOPs in the cleaning area, which could prevent its application because of reasons related to the efficiency of processes and the rationalization of work. An alternative that should be discussed in the scientific field is to advance from a SOP addressed to each type of product to the categorization of products by design, which would have a standard SOP. As an example, SOP for <5 mm lumen products and SOP for conventional surgical tweezers would make it easier to separate and direct the workflow in the cleaning area, whereas specific SOPs would be addressed to exotic or delicate products, such as products with electronic components and hydrodissection cannulas for ophthalmological surgery.

Sterilization level in samples with dirtiness

Unlike the expected, the samples, even with residual dirtiness, did not allow the recovery of microorganisms. A similar study contaminated the cannulas for meniscus repair with 0.5 mL of blood containing 200–500 cfu of coagulase-negative *Staphylococcus*, which were tested in three SOPs:

1. Manual cleaning and rinsing in the operating room, sterilization in the unwrapped flash cycle (132°C for 10 minutes);
2. Cleaning and rinsing with enzymatic detergent, pressure water jet, sterilization (132°C for 45 minutes);
3. Cleaning in ultrasonic cleaner, sterilization (132°C for 45 minutes).

No microorganism was recovered after these procedures; however, the authors still observed blood in the cannulas processed in SOPs 1 and 2[1]. These results reinforce the possibility of a product being without viable microorganisms, even with the adhered organic matter, although it cannot be considered safe for use due to the biological response, such as systemic inflammatory response syndromes and toxic anterior segment syndrome.

Another study showed dirtiness in cannulated products from the DePuy Mitek® Intrafix system, with positive culture for coagulase-negative *Staphylococcus*, *S. epidermidis* and *S. mitis*. In this study, the authors identified that the CSSD did not have brushes with the proper diameter to remove the dirt of the instrument[2], and this fact indicates a major deviation in good practices of health product processing. There was no mention to the monitoring of the steam sterilization process, so it was not possible to make other interpretations of the results obtained.

In 2011, during an outbreak of infections associated with flaws in the processing of orthopedic surgery instruments, the authors mentioned residues of organic matter and brush bristles in the products, besides the non-adherence to good practices, as the arthroscopy cannulas were only washed with tap water. Another important aspect is that, even with the observance of the SOPs provided by the manufacturer, some products still had residues of organic matter[3]. In this study, the fact that the residues were found in places whose visualization was only possible through a borescope was remarkable. That means that the visual inspection of the external surfaces of the products with internal spaces was not effective, reinforcing the need to invest in technologies of visualization in the preparation area, cleaning monitors, and qualification of automatic cleaning equipment, according to the Brazilian legislation[7]. Besides, the accessible design for cleaning and the validation of the practical application of SOPs are important to mention, because, in the aforementioned study, the instructions of the manufacturer were not efficient.

Cytotoxic residue

Sterilization is a critical safety aspect of medical devices; however, it is not the only one, because, even if sterile, a product can be toxic to the body. In the processes of cleaning validation, the possibility of reaching the "absolute zero" in organic residues is ruled out, even though reductions of about 99% have been reported[8]. Therefore, it is essential that the biological response to that residual dirtiness, even if minor, be demonstrated, so that a processed product can be considered safe, as proposed by laboratory studies of SOP validation[10,11].

In the obtained data, the toxicity of residual dirtiness obtained degree 3, which is therefore an unacceptable risk for use in surgical procedures, emphasizing the thesis that if a product cannot be cleaned, it cannot be safely reused.

CONCLUSION

The SOP used, elaborated in the best sequence of steps, in accordance with the practicable, was ineffective; flexible intramedullary reamers did not show the recovery of *Geobacillus stearothermophilus*; however, residual dirtiness had a cytotoxic effect. Therefore, the results sustain the discontinuity of

the flexible design due to the lack of safety in the reprocessing. It is important to mention that this fact should be considering by the committees of health products reprocessing, and also by all surgical teams, product manufacturers, and regulating institutions.

ACKNOWLEDGMENTS

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