Manual cleaning of flexible intramedullary reamers: process evaluation and protocol development

Limpeza manual de fresas intramedulares flexíveis: avaliação do processo e elaboração de protocolo

Limpieza manual de fresas intramedulares flexibles: evaluación del proceso y elaboración de protocolo

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ABSTRACT: Objective: To evaluate the manual cleaning process of flexible intramedullary reamers using the adenosine triphosphate (ATP) surface and water test and to develop a cleaning protocol for flexible intramedullary reamers used in orthopedic surgeries. **Method:** Experimental field study, with quantitative data analysis, carried out at the Central Sterile Supplies Department (CSSD) of a public hospital in Eunápolis, in the interior of Bahia. 32 reamers were evaluated, used in 17 orthopedic surgeries, before and after the cleaning process, totaling 64 ATP measurements on the surface and lumen. As a cleaning parameter, the recovery of up to 200 Relative Light Units (RLU) was adopted. To process the data, the generalized estimating equation model was considered for the RLU measurements and a significance level of 95%. **Results:** When comparing the surface and lumen RLU of dirty and clean reamers, there was a significant reduction of 230,997.18 surface RLU and 152,842.54 water RLU ($p<0.001$). The average recovery of the RLU of the reamers after cleaning was 74.3 RLU for the surface and 90.3 RLU for the lumen. **Conclusion:** Manual cleaning of flexible reamers required additional steps to achieve the RLU recovery adopted in the study. The validation of the immersion time in the enzymatic detergent and the step-by-step procedures used in cleaning allowed the evaluation of the process and the elaboration of the protocol for manual cleaning of the reamers.

Keywords: Decontamination. Orthopedic Procedures. Adenosine triphosphate. Material resources in health.

RESUMO: Objetivo: Avaliar o processo de limpeza manual de fresas intramedulares flexíveis por meio do teste adenosina trifosfato (ATP) superfície e água e elaborar um protocolo de limpeza de fresas intramedulares flexíveis utilizadas em cirurgias ortopédicas. **Método:** Estudo de campo, experimental, com análise quantitativa dos dados, realizado no Centro de Material e Esterilização (CME) de um hospital público de Eunápolis, interior da Bahia. Foram avaliadas 32 fresas, utilizadas em 17 cirurgias ortopédicas, antes e depois do processo de limpeza, totalizando 64 medidas de ATP na superfície e no lúmen. Como parâmetro de limpeza, adotou-se a recuperação de até 200 Unidades Relativas de Luz (URL). Para o tratamento dos dados, considerou-se o modelo de equação de estimação generalizada para as medidas de URL e nível de significância de 95%. **Resultados:** Ao serem comparadas as URL da superfície e do lúmen das fresas sujas e limpas, verificou-se redução significativa de 230.997,18 URL da superfície e 152.842,54 URL da água ($p<0,001$). A média de recuperação das URL das fresas após a limpeza foi de 74,3 URL para a superfície e 90,3 URL para o lúmen. **Conclusão:** A limpeza manual de fresas flexíveis demandou passos adicionais para alcançar a recuperação de URL adotada no estudo. A validação do tempo de imersão no detergente enzimático e o passo a passo dos procedimentos empregados na limpeza permitiram a avaliação do processo e a elaboração do protocolo de limpeza manual das fresas.

Palavras-chave: Descontaminação. Procedimentos ortopédicos. Trifosfato de adenosina. Recursos materiais em saúde.

RESUMEN: Objetivo: Evaluar el proceso de limpieza manual de fresas intramedulares flexibles, utilizando la prueba de superficie y agua de adenosina trifosfato (ATP), y elaborar un protocolo de limpieza para fresas intramedulares flexibles utilizadas en cirugías ortopédicas. **Método:** Estudio experimental de campo, con análisis de datos cuantitativos, realizado en el Centro de Materiales y Esterilización (CME) de un hospital público en Eunápolis, en el interior de Bahía. Se evaluaron 32 fresas, utilizadas en 17 cirugías ortopédicas, antes y después del proceso de limpieza, totalizando 64 mediciones de ATP en superficie y lumen. Se adoptó como parámetro de limpieza la recuperación de hasta 200 Unidades Relativas de Luz (URL). Para procesar los datos,

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se consideró el modelo de ecuación de estimación generalizada para las mediciones de URL y un nivel de significancia del 95%. **Resultados:** Al comparar el URL de superficie y lumen de las fresas sucias y limpias, hubo una reducción significativa de 230.997,18 URL de superficie y 152.842,54 URL de agua (p<0,001). La recuperación promedio de las URL de las fresas después de la limpieza fue de 74,3 URL para la superficie y 90,3 URL para el lumen. **Conclusión:** La limpieza manual de las fresas flexibles requirió pasos adicionales para lograr la recuperación de URL adoptada en el estudio. La validación del tiempo de inmersión en el detergente enzimático y el paso a paso de los procedimientos utilizados en la limpieza permitieron la evaluación del proceso y la elaboración del protocolo de limpieza manual de las fresas.

Palabras clave: Descontaminación. Procedimientos ortopédicos. Adenosina trifosfato. Recursos materiales en salud.

INTRODUCTION

In the daily operations of Central Sterile Supplies Departments (CSSD), whether public or private, there is a notable demand for processing orthopedic material, a demand closely related to the high prevalence of care provided to trauma patients.

Orthopedic surgery is closely intertwined with the burgeoning innovation of synthetic materials and prosthetics. The treatment of fractures has evolved substantially[1]. Current surgical techniques include locking screws and plates, locked intramedullary nailing (LIMN), and the use of image intensifiers, all contributing to increasingly modern approaches in orthopedic procedures.

Flexible intramedullary drills, used in orthopedic surgeries to fix fractures of long bones, are complex-shaped medical devices (MD) that can be processed and are heat-resistant[2].

The flexible design of this product is achieved through two stainless steel bands overlapping in a spiral configuration. Its non-detachable metal structure features grooves, folds, and lumens that are difficult to access for cleaning[2], which can lead to successive inadequate cleaning, increased waste, and formation of biofilms, thereby posing a risk to the processing of the material[3,4].

To assess the cleaning process, a variety of chemical tests are commercially available[5,6]. Among these, the adenosine triphosphate (ATP) test has emerged as a prominent tool in the daily practice of CME. This test offers quantitative, rapid, and objective results, facilitating immediate corrections in the cleaning process[7].

Considering adequate cleaning of complex conformation devices essential to guarantee processing safety, the present study intended to validate the manual cleaning process of flexible intramedullary reamers, using the ATP bioluminescence chemical test, and to develop a cleaning protocol validated for use in a CSSD of a medium-sized public hospital, located in the interior of Bahia.

OBJECTIVE

To assess the manual cleaning process of flexible intramedullary reamers, using the ATP test, and to develop a protocol for the manual cleaning of flexible intramedullary reamers used in orthopedic surgeries.

METHOD

Ethical-legal aspects

Approval of the project by the Research Ethics Committee was not necessary, as it did not involve human subjects. However, adhering to ethical and legal principles involving all types of research, the project was analyzed and approved by the Research Project Management System of the authors' affiliated institution, under number 5160/2021. Additionally, approval was obtained from the host institution of research, facilitated through the management of the surgical block, of which the CSSD is part.

Type and location of study

This is a field study, of experimental design, with quantitative analysis, carried out in the CSSD of a medium-sized tertiary hospital, which provides care via the Brazilian Unified Health System (*Sistema Único de Saúde* – SUS), managed by the city hall of the municipality of Eunápolis, located in the extreme south of Bahia, Northeast Region of Brazil.

The cleaning process is manual, in accordance with the current CSSD scenario. It involves utilizing running drinking water, a sponge for delicate cleaning, nylon brushes with soft bristles for surface cleaning, and cannulae with stainless steel rods of specific diameters corresponding to each lumen of the reamer. Additionally, rinsing is done through jets of

distilled water under pressure, followed by drying with sterile compresses and a jet of compressed air.

The Ciclozyme Extra® detergent was diluted at a ratio of 4 mL per liter of distilled water, in accordance with the manufacturer's instructions. As CSSD lacks water at a temperature between 30 and 40°C, it became necessary to validate the immersion time for water at room temperature, as recommended by the manufacturer.

During the cleaning process, drinking water was used and, for the final rinse, a jet of distilled water, chemically pure and free from soluble salts, was employed.

Sample/material

The sample was defined by convenience, considering the number of orthopedic surgeries that used flexible intramedullary reamers over a six-month period, from September 2022 to February 2023. The study encompassed 32 flexible reamers, used in 17 orthopedic surgical procedures.

At the outset of the study, a pre-test was carried out to determine the immersion time in the enzymatic detergent, with options of 10, 20, and 30 minutes, aimed at validating the immersion time as recommended by the product manufacturer. Therefore, processes with an immersion time of less than 30 minutes were disregarded for the comparison of RLU reduction, resulting in the inclusion of 56 measurements.

The flexible reamers are included in the consigned material for orthoses, prostheses, and special materials (OPSM) at the study institution, provided by a third-party company, and are exclusively available to the institution for a period of 12 months. They are made of 316 L stainless steel and nickel titanium alloy (Nitinol) and are characterized by an intramedullary and modular milling head, ranging from 9.0 to 14.00 mm, with increments of 0.5 mm, suitable for femoral or tibial use[8].

There is no pre-established processing limit for flexible reamers in the study scenario. Their use is unrestricted, and they are replaced when they sustain damage and lose functionality, based on the criteria set by the orthopedic surgeon. Therefore, there was no opportunity to carry out prior control of the processing number of the studied reamers.

Operationalization of data collection

To document data collection, a form was employed to record the results of the ATP bioluminescence test in Relative Light Units (RLU) and process time parameters. These parameters included immersion time of the reamers in the enzymatic detergent, arrival time of the reamers at the purge before the end of the surgery, cleaning time and arrival time of the orthopedic boxes in the purge after the end of the surgery.

For the evaluation and validation of the cleaning process, the 3M Clean-Trace™ Surface ATP and 3M Clean-Trace™ Water Total ATP test were used. These tests were conducted using a 3M™ Clean-Trace™ ATP LX25 Luminometer device for reading RLU[9], manufactured by 3M Health Care Bridgend, Wales, United Kingdom, and distributed by *3M do Brasil Ltda*., under CNPJ 45.985.371/0001-08.

The results of the ATP bioluminescence test in RLU were recorded both before and after the manual cleaning processes of the reamers, carried out in accordance with the current CSSD scenario.

Initially, the study author underwent training on the operational procedure for carrying out ATP bioluminescence tests, as well as the handling and specific care required for the Luminometer device. The device was calibrated and operated in accordance with standard protocols.

3M recommends performing the ATP reading on a new device. With this, a measurement of ATP was collected both on the surface and in the lumen by rinsing 40 mL of distilled water from a new, sterilized flexible intramedullary reamer.

Given the scarcity of scientific references relating the ATP test to the verification of cleaning of flexible reamers, a recovery of up to 200 RLUs was established as a cleaning parameter for the research. This threshold aligns with studies that validated the cleaning of critical MD of complex conformation using ATP bioluminescence, utilizing this benchmark[10,11].

Statistical analysis

Times were reported based on means, standard deviations, minimum and maximum values, medians, and quartiles. The comparisons of the RLUs between the milling reamers were verified according to generalized estimation equation models, considering the dependence between measurements of the same milling reamer using Gamma distribution. These models considered the effect of the moment of measurement, distinguishing between dirty and clean reamers. The results were presented as estimated means and 95% confidence intervals (95% CI) per measure. The analyses were carried out using the Statistical Package for the Social Sciences (SPSS), version 26.0, considering a significance level of 5%.

RESULTS

Reamers were collected from 17 surgeries, two per surgery: the first and last used in each procedure. In some surgeries, only one reamer was required to achieve the optimal milling of the spinal canal for nail implantation. Hence, a total of 32 flexible intramedullary reamers were analyzed. Each reamer underwent surface and water RLU measurements, first with the dirty reamer (post-use) and then after the manual cleaning process, in order to compare the RLU reduction during cleaning. This resulted in a total of 64 measurements. RLU measurements were performed on the same group of dirty and clean reamers.

To compare the reduction in RLU, processes with immersion time of less than 30 minutes were disregarded, resulting in 56 measurements being included for comparison.

Soaking time in enzymatic detergent

Comparing the reduction in URL obtained at different immersion times in the enzymatic product, there was a reduction of 38,837.5 URL with an immersion time of 10 minutes, 68,794 URL with an immersion time of 20 minutes, and 230,997.2 URL with a 30-minute immersion time. All reductions were found to be significant at the 1% level.

Table 1 presents all immersion times to emphasize that, despite the significant results observed with all three durations, 30 minutes of immersion time was considered as standard for the study, achieving the best recovery result for the adopted cleaning parameter (200 RLU).

When comparing the average RLU of the water at different immersion times, there was a significant reduction of 860.5 RLU with an immersion time of 10 minutes, 1,901.8 RLU with a time of 20 minutes, and 28,765.1 RLU with an immersion time of 30 minutes (Table 2).

Reduction of relative light units

Table 3 provides descriptions of the collected measures. The median number of RLUs on the surface of dirty reamers was 202,082 RLUs, ranging from 6,714 to 496,441 RLUs. After cleaning, the median was 47 RLUs, ranging from 13 to 299 RLUs. For water RLUs, the median number of dirty reamers was 112,880.5 RLUs, ranging from 3,642 to 493,968 RLUs. After cleaning, the median was 51.5 RLUs, ranging from 15 to 287 RLUs.

Table 4 presents the comparison of the RLU of dirty and clean reamers, measured on the surface and in the water. There was a significant reduction of 230,997.18 surface RLU (95%CI 173,975.8–288,018.5) and 152,842.54 water RLU (95%CI 96,463.9–209,221.1).

Arrival time at purge

The arrival time of the orthopedic boxes at the purge, the arrival time of the reamers, the difference between these times, and the cleaning time were calculated.

The cleaning process of the reamers was initiated before the end of the surgery to minimize residue retention. Therefore, the reamers were collected from the operating room immediately after use, rather than waiting for the orthopedic boxes to arrive after the end of the surgery, as was routine before the present study.

Therefore, comparing the different arrival times of the material aimed to demonstrate that the average time for the orthopedic

Table 1. Estimated mean values and 95% confidence intervals for the differences in Relative Light Units on the surface before and after cleaning the intramedullary reamers, by immersion time in the enzymatic detergent.

	Contrasts			Estimated mean difference (95%CI)	p-value
10 min	Clean	x	Dirty	-38,837.5 (-42,322.4; -35,352.6)	**<0.001**
20 min	Clean	x	Dirty	-68,794 (-114,641.1; -22,946.9)	**0.003**
30 min	Clean	x	Dirty	-230,997.2 (-288,018.5; -173,975.8)	**<0.001**
Clean	10 min	x	20 min	-127 (-308.2; 54.2)	0.170*
		x	30 min	-263.7 (-179.2; -348.2)	**<0.001***
	20 min	x	30 min	-390.7 (-195.5; -585.9)	**<0.001***
Dirty	10 min	x	20 min	-30,083.5 (-75,899.2; 15,732.2)	0.198*
		x	30 min	-191,896 (-261,687.5; -122,104.5)	**<0.001***
	20 min	x	30 min	-161,812.5 (-245,370.8; -78,254.2)	**<0.001***

*p-values corrected by the Bonferroni method. Bold indicates statistically significant p-values.

Table 2. Estimated mean values and 95% confidence intervals for the differences in Relative Light Units of water before and after cleaning the intramedullary reamers, by immersion time in the enzymatic detergent.

	Contrast			Estimated mean difference (95%CI)	p-value
10 min	Clean	x	Dirty	-860.5 (-5,467.6; -2,094.4)	**<0.001**
20 min	Clean	x	Dirty	-1,901.8 (-10,851.9; -3,397.1)	**<0.001**
30 min	Clean	x	Dirty	-28,765.1 (-209,221.1; -96,464)	**<0.001**
Clean	10 min	x	20 min	-431 (-191; 1,053)	0.174*
		x	30 min	-979.3 (-813.7; -1,144.8)	**<0.001***
	20 min	x	30 min	-548.3 (-147.5; 1,244)	0.155*
Dirty	10 min	x	20 min	-2,912.5 (-7,613.8; 1,788.8)	0.225*
		x	30 min	-148,082.3 (-216,983.3; -79,181.3)	**<0.001***
	20 min	x	30 min	-145,169.8 (-209,836.3; -80,503.3)	**<0.001***

*p-values corrected by the Bonferroni method. Bold indicates statistically significant p-values.

Table 3. Descriptive measurements of Relative Light Units, before and after the manual cleaning process of intramedullary drills (n=56).

	Reamers	
	Dirty	Clean
Surface RLU		
Mean (standard deviation)	231,071.5 (156,789.9)	74.3 (64)
Minimum-maximum	6,714–496,441	13–299
Median [quartiles]	**202,082 [107,913.5; 341,173]**	**47 [34.5; 103.5]**
Water RLU		
Mean (standard deviation)	152,932.8 (155,008.5)	90.3 (80.4)
Minimum-maximum	3,642–493,968	15–287
Median [quartiles]	**112,880.5 [13,054.5; 238,422]**	**51.5 [31; 143]**

*In bold, the most appropriate measures are highlighted, according to the distribution.

Table 4. Comparison of Relative Light Units measurements before and after manual cleaning of intramedullary reamers (n=56).

Measure	Estimated mean	95%CI		p-value
		Lower	Upper	
Surface RLU				
Dirty	231,071.50	180,535.60	295,753.51	**<0.001**
Clean	74.32	54.34	101.66	
Water RLU				
Dirty	152,932.79	105,777.50	221,109.76	**<0.001**
Clean	90.25	65.28	124.78	

RLU: Relative Light Units. Bold indicates statistically significant p-values.

boxes to reach the purge was 140.4 minutes, with a standard deviation of 40.1 minutes, ranging from 70 to 231 minutes. This time was almost double the time it took for the reamers to arrive at the purge, which had an average of 75.1 minutes, with a standard deviation of 30.7 minutes, ranging from 28 to 127 minutes.

The average difference between times was 65.4 minutes, with a standard deviation of 29.6 minutes, ranging from 19 to 124 minutes. The average cleaning time for the reamers was 65.1 minutes, with a standard deviation of 8.9 minutes, ranging from 45 to 84 minutes (Table 5).

Table 5. Material time of arrival and intramedullary reamer cleaning process (in minutes).

Time of arrival of orthopedic boxes after surgery is complete	
Mean (standard deviation)	140.4 (40.1)
Minimum-maximum	70–231
Median [quartiles]	138 [115; 164]
Time of arrival of the reamers at the purge before the end of the surgery	
Mean (standard deviation)	75.1 (30.7)
Minimum-maximum	28–127
Median [quartiles]	72 [51; 95]
Difference between time of arrival at purge	
Mean (standard deviation)	65.4 (29.6)
Minimum-maximum	19–124
Median [quartiles]	66 [43; 85]
Cleaning time	
Mean (standard deviation)	65.1 (8.9)
Minimum-maximum	45–84
Median [quartiles]	65 [60; 70]

DISCUSSION

In recent years, the complexity in MD design has increased significantly and infection outbreaks related to contaminated devices have drawn attention to the need to control and monitor the procedures involved in the cleaning stage[12-14].

Indeed, the literature has revealed that the method of visual monitoring with the aid of an image intensifying magnifying glass most commonly used in practice has limitations, especially in the case of complex MD with intricate designs and narrow lumens, generating subjectivity to the result[15]. Thus, the application of rapid cleaning tests in CSSD routine can ensure regular monitoring of cleaning effectiveness, detecting organic residues, such as proteins, hemoglobin, and carbohydrates in surgical instruments[6].

The study utilized the ATP bioluminescence chemical method to validate the manual cleaning of flexible intramedullary reamers in public hospital's CSSD, where automated washers were not available. The aim was to establish a validated manual cleaning protocol for these medical instruments.

ATP is the main source of energy in all cells of living organisms. This monitoring system uses ATP luminescence to measure the presence of organic matter on environmental surfaces, instruments, endoscopes, and cannulated devices. The results are presented in RLU and the amount of light is proportional to the degree of contamination present in the sample. ATP reading is performed using a portable Luminometer device[16].

To validate the process and establish a manual cleaning protocol, the immersion time of the reamers in the enzymatic detergent was initially validated.

Brazilian legislation regulating the use of enzymatic detergents for cleaning MD determines that the immersion time in the enzymatic solution, as well as the quality and temperature of the water for dilution, must comply with the product manufacturer's instructions[17]. The manufacturer of the product used in this study recommends validating the immersion time with distilled water at room temperature. Consequently, it was found that immersing the reamers in the enzymatic detergent for 30 minutes resulted in a more substantial reduction in RLU compared to immersion times of 10 and 20 minutes.

Manual cleaning was carried out according to the instructions for use (IFU) of the manufacturer of the reamer supplied to the hospital[18].

Studies demonstrate that the ATP bioluminescence method provides evaluation of the parameters that go beyond visual cleaning, allowing real-time assessment of cleaning protocols[7,10,11,16].

The findings of this study align with existing literature. By analyzing ATP measurements on the surface and lumen of the reamers before and after the cleaning process, in line

with the IFU, actions were implemented to enhance the current CSSD process.

While rapid ATP tests have been employed to assess the effectiveness of cleaning surgical instruments, further studies are needed to establish an RLU cutoff that reliably indicates adequate cleaning has been attained[6,10].

ATP concentrations below 500 RLU have been deemed acceptable for clean surfaces[19]. However, in this research, a recovery threshold of up to 200 RLU was used as an acceptable cutoff point. This decision was based on scientific references that validated the cleaning of MD with complex conformation (flexible endoscopes and videolaparoscopic instruments), using this benchmark with the 3M Clean-Trace™ ATP test[10,11].

The manual cleaning process used for flexible reamers facilitated the recovery of the expected RLU. Following cleaning, the median reduction in RLU on the surface of the reamers was 47 RLU, while in water, the median reduction was 51.5 RLU.

The National Health Surveillance Agency (*Agência Nacional de Vigilância Sanitária* – ANVISA) recommends that manual cleaning of this type of MD be complemented by an automated washer[20]. A study shows that automated cleaning is more efficient and reproductive when compared to manual cleaning[21]. However, in most Brazilian hospitals, manual cleaning is the only method available[22], as in the hospital where this research was carried out. However, ANVISA considers that CSSDs should only process MD compatible with its technical capacity and infrastructure classification[20].

While it is widely recognized that disinfection or sterilization efforts will falter if cleaning procedures are ineffective, research indicates that there has been limited advancement in establishing comprehensive guidelines for monitoring cleaning efficacy, whether through manual or automated methods, across various types of MD that undergo processing[6].

This study used the ATP bioluminescence test to validate the manual cleaning process of flexible intramedullary reamers. Comparing the reduction in RLU between dirty and clean reamers, measured on both the surface and in the water, it was found that the cleaning procedure led to a significant decrease in both surface and water measurements.

During intraoperative fixation of femoral and tibial fractures with an intramedullary nail, reamers are the first devices to be used, in order to roughen the medullary canal for implantation of the nail. Therefore, initiating cleaning promptly after surgical use, that is, before the end of the surgery, was deemed crucial for protocol development.

Moreover, existing literature underscores the challenge posed by dried organic matter in MD, exacerbating the complexity of the cleaning process. This challenge is particularly heightened in devices featuring intricate designs, with tubular structures and narrow lumens[21], a characteristic shared by the reamers studied.

In the context of the research institution, it was observed that the flexible reamers reached the purge approximately 75.1 minutes before the end of the surgery on average. This was nearly double the time it took for the orthopedic boxes to arrive at the purge. Given this considerable time difference, waiting until the end of the surgery to initiate the cleaning process was deemed unnecessary.

The average cleaning time for the reamers was 65.1 minutes; a long time, even starting the cleaning process as close to clinical use as possible. Although complexly formed MD require more elaborate cleaning protocols, a standard operating procedure (SOP) with many manual cleaning steps may have neglected steps, especially during peak times[2].

The extended cleaning time observed can be attributed to the inherent complexity of the material, which presents challenges in removing residues such as blood, marrow, and bone remnants from the procedure. Additionally, the absence of an ultrasonic washer to complement the cleaning process may have contributed. However, an experimental study has shown that even with both manual and automated cleaning methods proven effective, the intricate design of the reamers poses difficulties in achieving complete removal of debris[2].

Orthopedic surgery is linked to the growing innovation of synthetic materials and prosthetics and it is important to recognize that the treatment of fractures has evolved substantially. However, it is essential that MD manufacturers prioritize the design of materials that facilitate safe cleaning, rather than solely focusing on product functionality. Furthermore, they must provide clear, enforceable and validated cleaning protocols to ensure process safety.

When analyzing the number of surgeries using flexible reamers during the study period, a reduced sample was observed. This data can be attributed to the size of the hospital, the reduced quantity of orthopedic material, the surgical treatment chosen, structural problems, and the demand for this type of surgical procedure itself, given that diaphyseal fractures of long bones are, in most cases, injuries caused by high-energy trauma, occurring as a result of traffic accidents, falls, or interpersonal violence involving firearms[23], therefore, of variable occurrence.

In the context of the research host hospital, the consignment of OPSM material exclusively to the institution without rotation with other hospitals is observed. This arrangement is advantageous as it aligns with ANVISA regulations mandating centralized processing[20]. Centralization not only standardizes but also reduces variability in cleaning outcomes.

In view of the above, it is observed that a new MD cleaning paradigm requires rapid monitoring data and tools that guarantee patient safety as part of quality control.

Hence, monitoring and validating cleaning through the ATP bioluminescence chemical test can be regarded as a control variable for cleaning flexible intramedullary reamers in the CSSD routine, without replacing visual and microbiological assessments.

Study limitations

The limitations of the study encompass the sample type and size, inherent limitations of the ATP test, and financial constraints. Additionally, the absence of literature on the manual cleaning of intramedullary reamers poses a challenge, as recommendations typically focus on automated cleaning processes. However, this does not reflect the reality of many CSSDs in Brazil and worldwide.

Contributions to Perioperative Nursing

As a contribution to Perioperative Nursing, we aim to underscore the intricacies involved in cleaning orthopedic surgical devices for compliance with current quality and safety standards, even within the constraints of public hospital settings in Brazil. Additionally, the proposed protocol in this study, outlined as a Standard Operating Procedure (SOP) in the Appendix, can be implemented in smaller institutions lacking automated cleaning processes, a common reality in hospitals globally.

CONCLUSION

In the study scenario, manual cleaning of flexible intramedullary reamers used in orthopedic surgeries necessitated additional steps beyond the manufacturer's instructions for use to validate the process, in line with the adopted cleaning parameter.

The study showcases, through statistical analyses, that validating the immersion time of flexible intramedullary reamers in enzymatic detergent and following step-by-step cleaning procedures enabled the evaluation of the process and the development of a manual cleaning protocol. Utilizing the 3M Clean-Trace™ ATP surface cleaning test for reference, a significant reduction in URL measurements was observed after the manual cleaning process of the reamers, with a prior 30-minute immersion in enzymatic detergent.

CONFLICT OF INTERESTS

The authors declare no conflict of interests.

AUTHORS' CONTRIBUTIONS

APLP: Conceptualization, Data collection, Writing – original draft. RC: Project administration, Writing – review & editing, Supervision.

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APPENDIX – Standard Operating Procedure (SOP): Manual cleaning of flexible intramedullary reamers.

Type of Document	Standard Operating Procedure (SOP)	**POP CME HRE** – page 1/2
Title	Manual cleaning of a flexible intramedullary reamer	**Emission:** 06/20/2023 Eunápolis/BA

1. Objective

- To remove organic matter and dirt present in flexible intramedullary reamers in order to reduce microbial load and ensure the product's safety for handling, preparation, and sterilization.

2. Material

- Private laundry
- Surgical cap
- Closed shoes
- Protective goggles
- Surgical mask
- Procedure gloves
- Long pipe rubber glove
- Long-sleeved waterproof apron
- Enzymatic detergent
- Distilled water
- Soft sponge
- Brushes with nylon bristles for surfaces
- Lumen brushes with varying diameters
- 20 mL syringe

3. Description of procedures

1. Wash hands before and after activities.
2. Wear personal protective equipment – PPE.
3. Dilute 12 mL of enzymatic detergent in 3 L of distilled water in a container – dilution as recommended by the manufacturer of CicloZyme;

Type of Document	Standard Operating Procedure (SOP)	**POP CME HRE** – page 2/2
Title	Manual cleaning of a flexible intramedullary reamer	**Emission:** 06/20/2023 Eunápolis/BA

4. Pre-rinse the surface and lumen of the flexible reamer with running drinking water, flexing it so that it reaches the grooves.
5. Fully immerse the reamer in enzymatic solution.
6. Inject 20 mL of enzymatic solution into the reamer's lumen using a syringe;
7. After 30 minutes of immersion, friction the surface of the reamer with a soft sponge five times from proximal to distal (back and forth motion);
8. Rinse again with running water;
9. Begin brushing the surface (back and forth motion) ten times or until no residue is evident;
10. Start brushing the lumen with a brush specifically sized for each reamer's lumen (back and forth motion) ten times or until no residue is evident;
11. Thoroughly rinse the surface and lumen of the reamer using a jet of distilled water under pressure, flexing it until no more dirt and turbidity is evident;
12. Dry the surface and lumen with a sterile compress (45x50) and a medicinal compressed air gun to visualize residues on the surface and crevices of the reamer;
13. In case of dirt on the compress during drying, repeat the process starting from brushing the surface and lumen;

14. After effective cleaning, rinse the surface of the reamer with 70% alcohol using a sterile compress five times in a back and forth motion;
15. Perform visual inspection using a magnifying glass.

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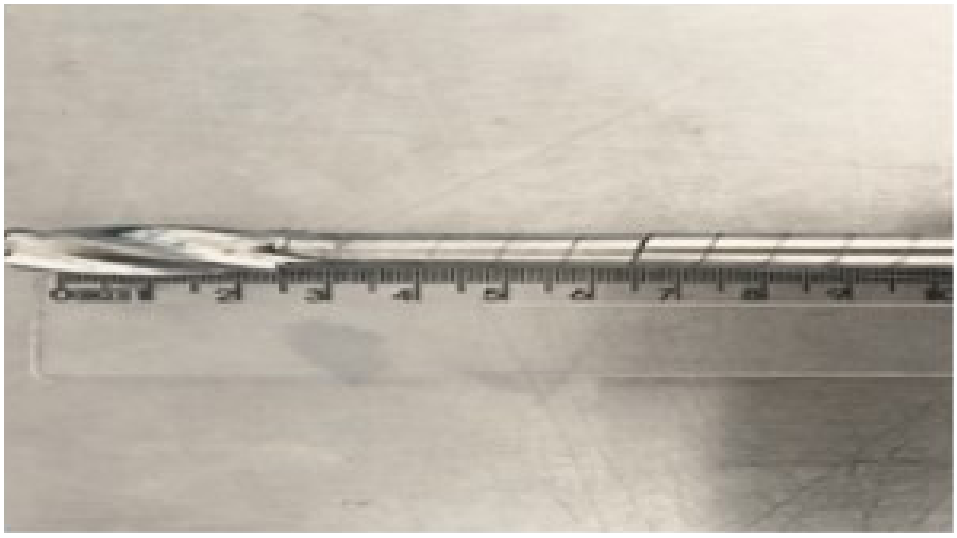
Procedure for collecting the adenosine triphosphate sample from the surface of the flexible reamer.

a) Perform hand hygiene.
b) Put on personal protective equipment – surgical mask and procedure gloves.
c) Remove the test from the refrigerator.
d) Remove the test from the aluminum packaging.
e) Wait for 10 minutes to reach room temperature.
f) Hold by the handle and remove the swab from the device.
g) Hold the reamer in a horizontal position.
h) Apply pressure on the swab in an area of 10 cm from the reamer – from the milling head to the body.
i) Rotate the swab longitudinally back and forth until completing a 360° turn on the reamer.
i) Reinsert the swab into the device in a vertical position.
j) Turn on the Luminometer and go to the collection item,
k) Push the swab handle to break the seal and activate the test.
l) Shake from side to side for 5 to 10 seconds, mixing the sample with the reagent.
m) Insert the 3M™ Clean-Trace™ ATP Surface test into the Luminometer, close the lid, and follow the instructions to take the measurement.
n) Wait for the values to be read in Relative Light Units (RLU).
o) Remove the test from the Luminometer and discard it.
p) Record the data on the research form.



Standardized area for collecting adenosine triphosphate from the surface of the flexible intramedullary reamer.

Procedure for collecting the adenosine triphosphate sample from the lumen of the flexible reamer

a) Perform hand hygiene.
b) Put on personal protective equipment – surgical mask and procedure gloves.
c) Open the sterile collector.
d) Hold the reamer in a vertical position without touching the sides of the collector.
e) Inject 40 mL of distilled water into the lumen of the reamer using a disposable syringe.
f) Close the collector with the rinse.
g) Remove the test from the refrigerator.
h) Remover o teste da embalagem aluminizada.
i) Wait for 10 minutes to reach room temperature.
j) Hold by the handle and remove the swab from the device.
k) Turn on the Luminometer and go to the collection item.
l) Open the collector and insert the test swab into the rinse, immersing it up to the collar without touching the sides or the bottom of the sterile container.
m) Wait 10 seconds for the sample to penetrate the rings.
n) Remove the test in the vertical position.
o) Reinsert the swab into the device in a vertical position.
p) Push the swab handle to break the seal and activate the test.
q) Shake from side to side for 5 to 10 seconds, mixing the sample with the reagent.
r) Insert the 3M™ Clean-Trace™ ATP Water test into the Luminometer, immediately close the lid, and follow the instructions to take the measurement.
s) Wait for the values to be read in Relative Light Units (RLU).
t) Remove the test from the Luminometer and discard it.
u) Record the data on the research form.