DOI: 10.11910/j.issn.2791-2043.2025.2.07

Study on Routine Inspection Method for Flexible Intramedullary Reamer and Its Impact on Reducing Risk of Surgical Site Infection

Wenru Huang[1], Xin Ju[1], Yunyu Jin[1*], Pengjiao Niu[2*]

(*1. Central Sterile Supply Department, The First Bethune Hospital of Jilin University, Changchun, Jilin, 130033, China*;
2. Central Sterile Supply Department, The First People's Hospital of Jinzhong , Jinzhong Shanxi, 030600, China)

ABSTRACT: Objective To explore the inspection methods for flexible intramedullary reamers (FIRs) to ensure cleaning quality and evaluate their potential value in reducing the risk of surgical site infection (SSI) in patients. **Methods** FIRs are categorized into "wave-type" and "thread-type" based on structural characteristics. FIRs used consecutively within the same medical institution were designated as Group A, while those used non-consecutively (by circulating across institutions) were as Group B. During the trial period, FIRs from both groups were cleaned according to a unified standard procedure. The turnover frequency and cleaning effectiveness of the two FIR types within the same institution were recorded for both groups. Cleaning quality was assessed using adenosinetriphosphate (ATP) bioluminescence assay and two types of visual inspection devices. **Results** Overall, the qualification rates for FIR surfaces and lumens via visual inspection were lower than those from the ATP bioluminescence assay for the corresponding areas (P<0.001). Comparative results from visual inspection devices showed that the cleaning qualification rate for wave-type FIRs was significantly higher than for thread-type FIRs (89.03% VS 73.39%, χ^2=11.14, P< 0.001); the cleaning qualification rate for Group A FIRs was significantly higher than for Group B (89.86% VS 73.28%, χ^2=12.39, P<0.001). Multivariate logistic regression analysis indicated that, after adjusting for cumulative usage count, instrument type (thread-type VS wave-type, odds ratios (OR) =3.21, 95% confidence interval (CI): 1.67~6.18, P<0.001) and usage mode (Group B VS Group A, OR=3.58, 95% CI: 1.84~6.97, P<0.001) remained independent risk factors for cleaning failure. **Conclusion** For lumens with complex structures, such as FIRs, only tested by ATP is insufficient to fully demonstrate cleanliness; visual inspection devices is recommended to introduce as a supplement. In addition, it is advised to establish and implement standardized cleaning procedures to ensure consistency and effectiveness of cleaning operations across different medical institutions. Furthermore, where conditions permit, wave-type FIRs may help achieve more reliable cleaning results, thus serving as one component of comprehensive measures to reduce the risk of surgical infection.

KEY WORDS: Loaner instrumentation; Lumen instrument; Cleaning quality; Surgical site infection

Introduction

Closed reduction and internal fixation with intramedullary nailing is a common procedure in traumatic orthopedic surgery, during which the flexible intramedullary reamer (FIR) is a key auxiliary instrument. Its primary function is to effectively enlarge the medullary cavity to facilitate the smooth insertion of the intramedullary nail, without damaging surrounding soft tissues or the bone cortex[1-2]. However,

First author: Wenru Huang
***Corresponding authors:** Correspondence to Yunyu Jin at 280824903@qq.com and Pengjiao Niu at npj258@163.com

after use, the surfaces, crevices, and internal lumens of FIR retain blood and bone debris. It is noteworthy that loaner medical device suppliers often fail to provide detailed cleaning instructions or matching dedicated cleaning tools, which undoubtedly adds extra challenges and pressure to cleaning by the Central Sterile Supply Department (CSSD)[3].

Surgical site infection (SSI) is a major complication of orthopedic surgery. Literature reports indicate its incidence varies by surgery type: 0.1%~1% for non-implant surgery, 1%~2% for primary joint replacement surgery, and 3%~10% for revision hip or knee surgery[4]. Given the close relationship between occurrence of SSI and instruments used during surgery[3,5-6], providing qualified sterilized instrument sets is the primary task of the CSSD, while reducing the SSI rate is a core goal of orthopedic surgery[4]. Ensuring thorough instrument cleaning is a prerequisite for successful sterilization. Any oversight in the cleaning process may lead to sterilization failure, thereby threatening patient safety and increasing the risk of hospital-acquired infections[6-7].

However, traditional cleaning quality inspection methods, such as visual inspection and inspection with lighted magnification, have obvious limitations in assessing instruments, such as FIRs, which have complex internal structures and intricate surface textures, making it difficult to effectively probe their internal cleaning status[8-9]. In recent years, adenosinetriphosphate (ATP) bioluminescence assay has been widely used for assessing the cleanliness of medical devices, but its efficacy for detecting non-biological contaminants and instruments with complex structures is debated[10]. Meanwhile, although studies have reported cleaning challenges for complex-structure instruments such as arthroscopic instruments and liposuction cannulae[11-13], systematic research on cleaning quality assessment is still insufficient specifically for these particular loaner, flexible, lumens, especially on comparing the impact of different structural designs (wave-type VS thread-type) and different usage management modes (consecutive VS non-consecutive) on cleaning effectiveness. Therefore, this study adopted a rigorous comprehensive testing strategy, integrating three detection methods: ATP bioluminescence assay, a Flexible Inspection Scope, and an Omni-Core Digital Microscope, aiming to accurately evaluate the cleaning quality of the two different types of FIRs, thereby reducing the risk of SSI in patients.

Methods

Study Objects

FIRs provided by loaner medical device suppliers were selected as the test objects. FIRs used consecutively within the same medical institution were designated as Group A, while those used non-consecutively (by circulating across institutions) were designated as Group B. Based on differences in surface crevice patterns, FIRs were divided into two types: “wave-type” (Figure 1A) and “thread-type” (Figure 1B). The study adopted convenience sampling. During the observation period from March 1, 2025, to June 1, 2025, a total of 264 pieces of FIRs were cleaned and tested. Sample size estimation was based on pre-trial results, with assumed cleaning qualification rates of 90% for the wave-type and 65% for the thread-type. Setting α= 0.05 (two-sided) and test power of 80%, it was calculated that at least 43 pieces per group were needed. The final sample size included in this study (155 pieces for wave-type pieces and 109 pieces for thread-type) meets this requirement. Considering the need for subgroup analysis, the current sample size is acceptable. Group A contained a total of 148 pieces of FIRs, including 91 for the wave-type and 57 for the thread-type; Group B contained a total of 116 pieces, including 64 for the wave-type and 52 for the thread-type.

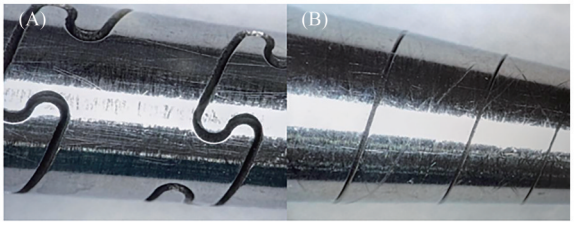

Figure 1 FIR Surface Patterns of Wave-type (A) and Thread-type (B)

Cleaning Method

The cleaning flowchart is shown in Figure 2, detailed as follows.

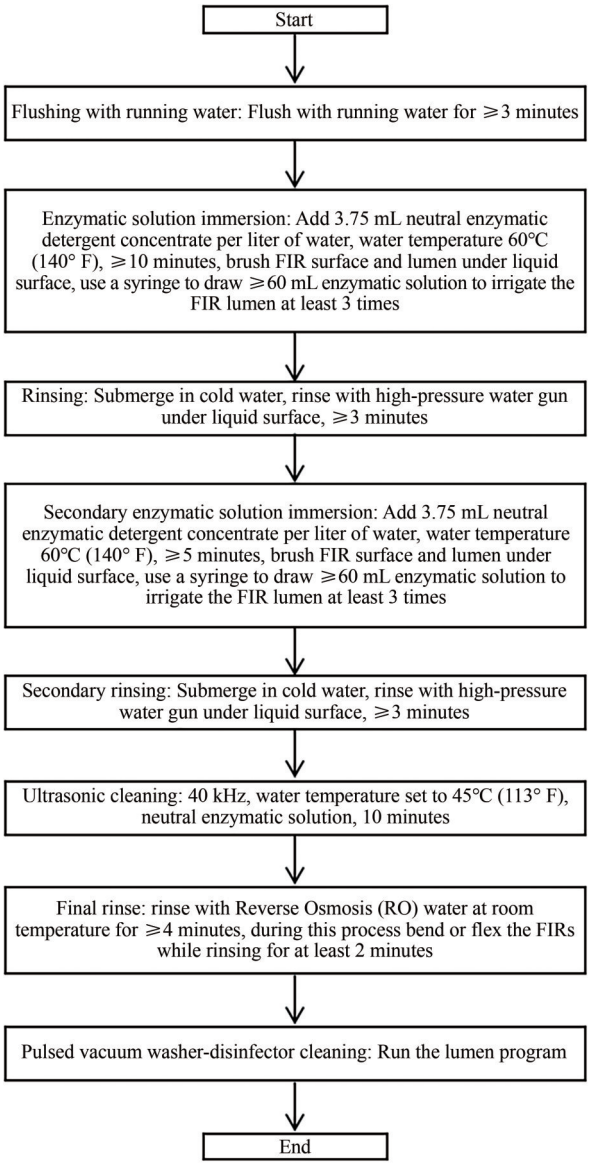

Figure 2 FIR Cleaning Flowchart

Step 1: Flushing with running water. FIRs were rinsed under running water for at least 3 minutes to preliminarily remove blood stains and tissue contamination from the FIR surface and lumen. During this process, the FIR lumen and surface crevices needed to be flushed.

Step 2: Enzymatic solution immersion. FIRs were immersed in a diluted neutral enzymatic detergent (Lapcholyzyme®, Ruhof, USA) solution (water temperature 60°C or 140°F, 3.75 mL of enzymatic detergent per liter of water) for at least 10 minutes. In the enzymatic solution, a soft-bristled brush was used to remove blood stains and tissue debris from the FIR surface and crevices; a 5mm medical lumen brush with a total length of 52 cm and a brush head length of 20 cm was used with a twisting motion, pushing and pulling to facilitate removal of stains inside the lumen. the lumen was flushed using a syringe filled with at least 60 mL of solution, at least three times.

Step 3: Rinsing. FIRs were removed from the enzymatic solution and placed in cold water, and a high-pressure water gun was used to agitate and rinse under the water surface for at least 3 minutes.

Step 4: Secondary enzymatic solution immersion. The neutral enzymatic detergent solution from Step 2 was prepared again. FIRs were placed in the neutral enzymatic detergent solution for at least 5 minutes. Brushing of the surface and lumen was performed under the liquid surface, and the lumen was flushed using a syringe filled with at least 60 mL of solution, at least three times.

Step 5: Secondary rinsing. The procedure was consistent with Step 3.

Step 6: Ultrasonic cleaning. An enzymatic detergent solution was prepared in an ultrasonic cleaner (40 kHz, DXQ6000 side-vibrating ultrasonic cleaner, SHINVA, Shandong, China). The water temperature was 45℃ (113°F), and FIRs underwent ultrasonic cleaning for 10 minutes. During ultrasonic cleaning, FIRs were completely immersed in the enzymatic solution, laid flat in a single layer in the cleaning basket, ensuring no overlap between instruments, and the load did not exceed 70% of the basket bottom.

Step 7: Final Rinse. At room temperature, Reverse Osmosis (RO) water was used to rinse FIRs for at least 4 minutes, with the rinsing lasting at least 2 minutes while bending or flexing the FIRs to ensure all surfaces were fully rinsed.

Step 8: Pulsed vacuum washing. The lumen cleaning program in a pulsed vacuum washer-disinfector (PC-C, SHINVA, Shandong, China) was run for washing and disinfection. During pulsed vacuum washing, FIRs were properly fixed on a

dedicated lumen rack, ensuring the lumen openings faced downward to facilitate drainage. Before running the cleaning program, it was checked and confirmed that the water level and detergent concentration in the washing chamber met equipment requirements.

During the trial, all FIR cleaning was performed by dedicated personnel. The above cleaning procedure requires attention. Because FIRs are flexible instruments, all flushing and brushing processes require the operator to rotate the FIR while simultaneously bending or flexing it in multiple directions to ensure all surfaces are fully flushed and brushed. To prevent aerosol generation, all flushing and brushing shall be performed under the liquid surface. Operators wear protective goggles.

Inspection Methods

During the trial, cleaning quality inspection of FIRs was performed independently by two dedicated personnel who had received uniform training. If results were inconsistent, a third senior assessor arbitrated, and the final result was based on the arbitration outcome.

1. ATP Bioluminescence Assay

Staff prepared a sterile field, sterile gloves, sterile scissors, sterile water, and a sterile kidney basin. A small amount of sterile water was poured into the sterile kidney basin. The sampler donned sterile gloves, took a disposable sampling swab with foam tip, moistened it with sterile water, inserted the 4 mm lumen sampling foam tip into the FIR lumen interior. During sampling, the FIR was bent to a certain curvature and the lumen sampling foam tip was repeatedly pulled back and forth 4 times in different directions. The foam tip was cut off into the sampling tube, the top was snapped to release the reagent, and after the reagent flowed to the bottom, the sampling swab stick was shaken for 3 seconds to allow the reagent to react with the sample. The sampling swab stick was then placed into the ATP monitor to read the data. This study took ⩽45 relative light unit (RLU), the threshold recommended by the Ruhof ATP Complete® contamination monitoring system instruction manual, to determine whether the FIR lumen cleaning was qualified, and >45 RLU was considered unqualified for lumen cleaning. This threshold is primarily set for ordinary smooth instruments, and thus this study explored its applicability in the complex structure of FIRs. Surface sampling method is to directly take the sampling swab stick from the sampling tube, moisten it with sterile water, bend the FIR to a certain curvature and change directions, and wipe the FIR surface 4 times with the swab tip.

2. Visual Inspection Devices

To assess inter-rater consistency, 20% of the samples (53 pieces) were randomly selected for independent blinded assessment by two evaluators. The results showed a Kappa value of 0.82 for the Flexible Inspection Scope assessment and 0.79 for the Omni-Core Digital Microscope assessment, indicating good consistency for both visual inspection methods.

Flexible Inspection Scope (FIS-005SK, Healthmark, USA): This method was used to inspect the interior of the FIR lumen. The probe lens was inserted into the FIR lumen interior. The light source brightness was adjusted according to the observation position. The workstation screen display was observed. A smooth lumen inner surface without foreign matter was considered cleaning qualified; the presence of rust spots, blood stains, dirt, scale, or other residues was considered cleaning unqualified. During observation, the location of discovered contaminants was photographed and recorded.

Omni-Core Digital Microscope (Ash Technologies, Ireland): This method was used to inspect the cleaning status of the external surface texture of the FIRs. The system magnification was set to 1∶20. The FIR was placed on the operation platform, the lens focus was adjusted, and the FIR was moved. Observing the screen display allowed viewing the cleaning quality of the complete surface crevices of the FIR. The observed contamination locations were photographed and recorded to ensure a detailed assessment of cleaning quality.

Statistical Analysis

IBM SPSS Statistics 25.0 statistical software

was used. Count data were expressed as numbers (percentages) and compared using the χ^2 test or McNemar's test. Furthermore, to explore independent risk factors for cleaning failure, taking "cleaning qualification status (Yes=0, No=1)" as the dependent variable, and instrument type (wave-type=0, thread-type=1), usage mode (Group A=0, Group B=1), and cumulative usage count (continuous variable) as independent variables, multivariate logistic regression analysis was performed. The corresponding odds ratios (ORs) and their 95% confidence intervals (Cis) were calculated. P<0.05 indicated that the difference was statistically significant.

Results

The comparison results of visual inspection devices and the ATP bioluminescence assay to assess FIR cleanliness are shown in Table 1 and Table 2.

A comparison of the cleaning qualification rates for the two different types of FIRs, based on visual inspection results, found that the cleaning qualification rate for wave-type FIRs was higher than for thread-type FIRs, and the difference was statistically significant. Specific data are shown in Table 3.

Similarly, comparing the cleaning qualification rates for FIRs in Group A and Group B based on visual inspection results, it is found that the cleaning qualification rate for Group A was higher than for Group B, and the difference was statistically significant. Specific data are shown in Table 4.

To further control for confounding factors, multivariate logistic regression analysis was performed. The results showed that, after adjusting for the influence of cumulative usage count, instrument type and usage mode remained independent risk factors for cleaning failure. Compared to wave-type FIRs, thread-type FIRs had a significantly higher risk of cleaning failure (OR=3.21, 95% CI: 1.67~6.18, P<0.001). Compared to Group A (consecutive use), Group B (non-consecutive use) also had a significantly higher risk of cleaning failure (OR=3.58, 95% CI: 1.84~6.97, P<0.001).

Visual inspection results revealed the distribution of contamination locations for the two types of FIRs as follows: Contaminants on the surface of wave-type reamers were distributed relatively evenly; contaminants on the surface crevices of thread-type reamers were mostly concentrated at both ends of the surface; contaminants inside the lumen of both

Table 1 Comparison of Omni-Core Digital Microscope and ATP Bioluminescence Assay in Evaluating FIR Cleanliness

Surface	ATP Bioluminescence Assay		Total (%)	χ^2	P
Omni-Core Digital Microscope	Qualified	Unqualified			
Qualified	222	2	224 (84. 85)		
Unqualified	35	5	40 (15. 15)	29. 43	P<0. 001
Total	257 (97. 35)	7 (2. 65)	264 (100. 00)		

Table 2 Comparison of Flexible Inspection Scope and ATP Bioluminescence Assay in Evaluating FIR Cleanliness

Lumen	ATP Bioluminescence Assay		Total (%)	χ^2	P
Flexible Inspection Scope	Qualified	Unqualified			
Qualified	233	0	233 (88. 26)		
Unqualified	28	3	31 (11. 74)	26. 04	P<0. 001
Total	261 (98. 86)	3 (1. 14)	264 (100. 00)		

Table 3 Comparison of Cleaning Qualification Rates Measured by Visual Inspection Device for Two Types of FIRs [N(%)]

FIR Type	Visual Inspection Result		Total	χ^2	P
	Qualified	Unqualified			
Wave-type	138 (89. 03)	17 (10. 97)	155 (100. 00)		
Thread-type	80 (73. 39)	29 (26. 61)	109 (100. 00)	11. 14	P<0. 001
Total	218 (82. 58)	46 (17. 42)	264 (100. 00)		

Table 4 Comparison of Cleaning qualification rates Measured by Visual Inspection Device for Group A and Group B FIRs [N(%)]

Group	Visual Inspection Result		Total	χ^2	P
	Qualified	Unqualified			
Group A	133 (89. 86)	15 (10. 14)	148 (100. 00)		
Group B	85 (73. 28)	31 (26. 72)	116 (100. 00)	12. 39	P<0. 001
Total	218 (82. 58)	46 (17. 42)	264 (100. 00)		

types were mainly concentrated in the "platform" at the structural transition points at both ends of the lumen interior. The platform position in the FIR and the structural differences between the two types of FIRs are shown in Figure 3; specific contamination distribution numbers and proportions are shown in Table 5. The types, morphology, and locations of contaminants on the surface and lumen of the two types of reamers are shown in Figure 4.

In this study, all FIRs that had failed the initial inspection (46 pieces in total) were re-cleaned targetedly and were re-inspected. All results reported qualified.

Discussion

ATP bioluminescence detection technology is based on the quantitative detection of ATP, a key intracellular energy carrier molecule. The liquid contained within the detection reagent stick includes a lysing agent. When this agent is released, it induces cell lysis, thereby releasing various intracellular substances, including ATP. Subsequently, the released ATP reacts with luciferase, and the reaction intensity is proportional to the ATP content, allowing the specific ATP content in the sample to be determined[9,14-15]. This is a rapid, efficient, highly sensitive method, capable of detecting very low levels of ATP in a short time, and provides quick results[16-18]. However, comparing the cleaning qualification rates of FIRs obtained by different inspection methods in Tables 1

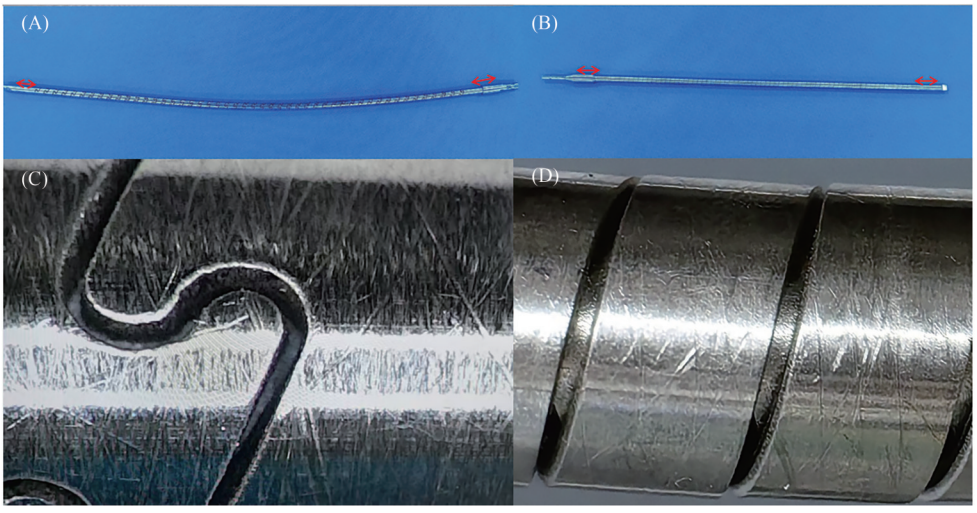

Figure 3 Wave-type (A), Thread-type (B), "↔" indicates the platform position within the FIR; the the wave-type FIR is single-layer, showing the white insert inside (C) by magnified view under the Omni-Core Digital Microscope; the the thread-type reamer is multi-layer, showing no white insert visible inside (D) by magnified view under the Omni-Core Digital Microscope.

Table 5 Distribution of Contaminant Locations for Two Types of FIRs

FIR Type	Contaminant Location	Number of Contaminated	Total Number Inspected	Contamination Rate (%)
Wave-type	Surface Middle	8	155	5. 16
	Surface Ends	21	155	13. 55
	Lumen Middle	5	155	3. 23
	Lumen Platform	12	155	7. 74
Thread-type	Surface Middle	5	109	4. 59
	Surface Ends	6	109	5. 50
	Lumen Middle	3	109	2. 75
	Lumen Platform	11	109	10. 09

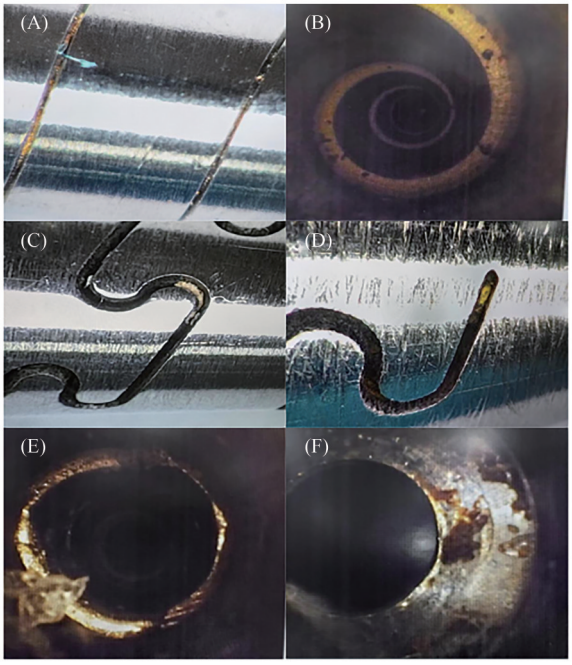

Figure 4 Rust and grease foreign matter in the middle section of the thread-type FIR surface crevice (A); multiple spots of grease-like foreign matter in the middle section of the thread-type FIR lumen (B); bone tissue residue in the middle section of the wave-type FIR surface crevice (C); grease foreign matter residue at one end of the wave-type FIR surface crevice (D); bone tissue residue in the middle section of the wave-type FIR lumen (E); accumulation of greas foreign matter on the "platform" at one end of the structural transition connection inside the FIR lumen (F).

and 2 reveals that, whether for the FIR lumen or surface, the ATP bioluminescence assay showed cleaning qualification rates close to 100% (Surface: 97.35%, Lumen: 97.86%), but the cleaning qualification rates obtained by the two visual inspection devices for the FIR surface and lumen dropped significantly (Surface: 84.45%, Lumen: 88.26%), indicating that visual inspection devices have a higher detection rate for stains. During the experiment, it was found that while ATP test results indicated that 35 pieces of FIR surfaces and 28 pieces of FIR lumens met the qualification standard, further inspection with visual inspection devices still revealed the presence of grease or tissue debris inside the lumen or within surface crevices. Analysis suggests that the ATP bioluminescence results might be attributed to two reasons. First, the ATP fluorescence detection method has some limitations and drawbacks and cannot detect non-biological contaminants such as grease, dust, metal particles, etc.; thus the measured value is influenced by chemical factors[10]. Second, whether for thread-type or wave-type FIRs, the crevices on their surfaces and within their lumens are very tight. Even when sampling was performed with multi-angle bending, situations existed where the sampling swab could not fully contact the crevice areas, potentially leading to false-negative results. Based on the data analysis from this experiment, only ATP method cannot fully ensure accurate assessment of FIR cleanliness.

The comparison of cleaning qualification rates for the two different types of FIRs in Table 3 shows that the cleaning qualification rate for wave-type FIRs was 89.03%, while for thread-type FIRs it was 73.39%. This difference was statistically significant. Multivariate logistic regression analysis further confirmed that, after controlling for confounding factors such as frequency of use, the thread-type structure was an independent risk factor for cleaning failure (OR=3.21). The Omni-Core Digital Microscope results (Figure 3) revealed that wave-type FIRs have a single-layer structure, whereas thread-type FIRs exhibit a multi-layer, non-disassemblable complex structure, with layers rotating in opposite directions and overlapping areas existing. This inherent complexity in design makes contaminants more likely to be trapped and difficult to remove thoroughly by routine cleaning processes, which may be the root cause for the lower cleaning qualification rate of thread-type FIRs. This is consistent with the research conclusions of Lopes[12] and Costa[13] regarding the difficulty of cleaning complex-structure instruments. This study further quantifies the impact degree of this specific structural difference on the cleaning qualification rate.

The comparison of the cleaning effectiveness of FIRs in Group A and Group B (Table 4) found that the cleaning qualification rate for Group A was 89.86%, significantly higher than the 73.28% for Group B. Similarly, multivariate analysis results supported that "non-consecutive use" (Group B) was an independent risk factor for cleaning failure (OR=3.58). Data statistics on the distribution of contamination locations show that by inspection of

the FIR surface using the Omni-Core Digital Microscope, the crevice ends of wave-type FIRs (Table 5, contamination rate of 13.55%) were prone to residue of bone debris or grease foreign matter, as shown in Figure 4(D), representing overlooked points and weak spots in the cleaning of wave-type FIRs. Inspection using the Flexible Inspection Scope found that both types of FIRs have a "platform" at the internal structural transition points at both ends, presented in Figure 4(F). This platform is the primary site for contaminant accumulation. Data statistics on contamination location distribution indicate that this is the main reason for the lower lumen cleaning qualification rate in FIRs not used consecutively within the same medical institution. This may be occurred because when FIRs circulate among different medical institutions, the emphasis placed on FIR cleaning and the cleaning procedures implemented vary between institutions, leading to difficult-to-remove stain residue in the platform[18-20]. This speculation needs further verification through multicenter studies in the future, combined with on-site inspections or questionnaire interviews regarding the cleaning processes of various hospitals. The Flexible Inspection Scope can directly display the degree and location of contaminant residue[11,21-22], contributing to identifying difficulties and oversights in cleaning, and allowing for targeted handling of instrument residual contaminants[23-24]. Visual inspection can only detect contaminants larger than 50 micrograms on the instrument surface or shallow positions, while dispersed, minute, or internal lumen contaminants are difficult to observe[25]. Therefore, visual inspection devices can effectively help identify cleaning quality issues with instruments. Through targeted re-cleaning processes, all instruments that failed the initial cleaning could meet the qualification standard, indicating that although standard processes pose challenges for complex instruments, their cleaning quality is controllable through enhanced quality control and feedback mechanisms. For example, more attention should be paid to brushing the platform, and FIRs used intermittently within the same medical institution should be brushed repeatedly. The difference in cleaning qualification rates between consecutively used and intermittently used FIRs within the same institution also highlights the importance of establishing standardized cleaning procedures. By establishing standardized procedures, cleaning qualification rates can be improved, thereby ensuring cleaning quality[20].

This study holds certain implications for clinical practice and policy formulation. Firstly, the results strongly suggest that complex loaner instruments, such as FIRs, should not be tested only by ATP assay; visual inspection (e. g., borescopes, digital microscopes) should be incorporated into the routine quality control system as an effective supplement to ATP testing. Secondly, the study emphasizes the urgency of establishing and enforcing national or regional standardized cleaning procedures, especially for loaner instruments, and medical device suppliers should provide clear, verifiable cleaning instructions. Finally, in addition to considering clinical function, instrument procurement and selection should take the cleanability of the instrument should into consideration as an important evaluation criterion. The data from this study support the priority selection of structurally relatively simpler wave-type FIRs.

Limitations

This study has several limitations. First, although the sample size met the statistical requirements for the study objectives, the convenience sampling method may still introduce selection bias, and the generalizability of the research results should be treated cautiously. Second, this study is observational; although some confounding factors were controlled through multivariate analysis, there may still be unmeasured confounding variables (such as subtle differences in operation among different cleaning staff), thus the strength of causal inference from the conclusions is limited. Third critical parameters of the manual cleaning process (such as temperature, chemical concentration) were not monitored in real-time nor process challenge verified, which may affect the reproducibility of the results. Forth, this study

only adopted ATP and visual inspection, without employing quantitative methods such as protein residue (e.g., BCA method) or carbohydrate residue (e. g., anthrone method) for cross-validation, limiting the assessment capability for non-biological contaminants. Fifth, practical considerations of equipment cost and time cost were not explored in this study. Finally, this study only assessed the intermediate outcome of cleaning quality and did not directly track patient SSI outcomes; therefore, the conclusion of "reducing SSI risk" is inferred based on the recognized logic that "cleaning is a prerequisite for sterilization," rather than being direct evidence.

Conclusion

The FIRs studied in this project are loaner instruments rented to hospitals by external medical device suppliers and are typically not used consecutively within the same medical institution. If these instruments are not thoroughly cleaned over the long term, it may lead to biofilm formation and sterilization failure[6,26], thereby increasing the risk of postoperative intramedullary infection in patients. This not only poses a threat to patient health but may also impact infection control across multiple hospitals. Therefore, for complex-design reusable medical instruments, such as FIR, a single cleaning quality inspection method has limitations and potential risks. It is recommended to apply multiple inspection methods (especially visual inspection devices) for comprehensive assessment of the instrument lumen and surface to enhance the reliability of cleaning quality inspection. In addition, it is recommended that surgical instrument manufacturers, during their design phase, must consider not only the convenience of surgical operation but also prioritize the cleanability of the instrument, ensuring that the instrument can be thoroughly cleaned[27]. Based on the data from this study, it is suggested that prioritizing the use of wave-type FIRs in intramedullary nailing procedures may help achieve more reliable cleaning results. Meanwhile, to ensure homogeneity in cleaning quality, it is recommended that instrument manufacturers provide users with standardized cleaning procedures, and it is suggested that medical institutions and regulatory bodies incorporate cleaning verification (including the use of visual inspection devices) for such complex loaner instruments into mandatory quality control criteria. Through such comprehensive measures, the cleaning quality of medical instruments can be improved, providing a solid foundation for ensuring patient safety and the reliability of medical services.

Ethics and Conflict of Interest

This study was approved by the Ethics Committee of the First Hospital of Jilin University (Approval No. 2025-468). The instruments used in this study were reusable, and had been used in surgery and entered the CSSD for processing according to routine procedures. The sampling process did not involve any patient identification information or remaining clinical samples; only physical and chemical residues on the instruments themselves were tested, involving no patient privacy issues.

Conflict of Interest Statement

The Ruhof ATP detection system and consumables used in this study were sponsored free of charge by the manufacturers. Both the Flexible Inspection Scope and Omni-Core Digital Microscope are routinely equipped in the CSSD of our hospital. The authors declare no conflicts of interest that could affect the objectivity of this study.

References

[1] WANG J, LI H M, JIA H B, et al. Intramedullary versus extramedullary fixation in the treatment of subtrochanteric femur fractures: a comprehensive systematic review and meta-analysis[J]. Acta Orthop Traumatol Turc, 2020, 54(6): 639-646.

[2] PESANTE B D, STACEY S C, KIM Y J, et al. Single-use reamer shafts for intramedullary nail fixation: an addressable source of extraneous cost and medical waste in orthopaedic surgery[J]. J Orthop Trauma, 2023, 37 (12): 640-643.

[3] ZHENG S W, JIANG D, LIU P, et al. Management quality of surgical instrument and influence of cleaning

and sterilization on the surgical outcomes of the patient: a review[J]. Altern Ther Health Med, 2023, 29(8): 863-869.

[4] ANAZOR F, SIBANDA V, ALTAF K, et al. The impact of sterile instrument set wrapping defects on trauma and orthopaedic surgery theatre lists[J]. Cureus, 2022, 14(10): e29861.

[5] SCHÖMIG F, PERKA C, PUMBERGER M, et al. Implant contamination as a cause of surgical site infection in spinal surgery: are single-use implants a reasonable solution?- a systematic review[J]. BMC Musculoskelet Disord, 2020, 21(1): 634.

[6] OUIRUNGROJ T, APICHAI S, PATTANANANDECHA T, et al. Smart-detection approach for protein residues to evaluate the cleaning efficacy of reusable medical devices[J]. J Hosp Infect, 2024, 145: 44-51.

[7] LINK T. Guidelines in practice: instrument cleaning [J]. AORN J, 2021, 114(3): 241-251.

[8] HUANG J L, YI L Y, CHEN Y H, et al. Factors associated with cleaning quality of reusable medical devices at a single center in China[J]. Heliyon, 2024, 10(2): e24194.

[9] MASIA M D, DETTORI M, DERIU G M, et al. ATP bioluminescence for assessing the efficacy of the manual cleaning procedure during the reprocessing of reusable surgical instruments[J]. Healthcare (Basel), 2021, 9 (3): 352.

[10] SANNA T, DALLOLIO L, RAGGI A, et al. ATP bioluminescence assay for evaluating cleaning practices in operating theatres: applicability and limitations[J]. BMC Infect Dis, 2018, 18(1): 583.

[11] SANTOS R K D, POZZER C E, RABAIOLI C M, et al. Central sterile services department: screening of automated cleaning in liposuction cannulae[J]. Rev Gaucha Enferm, 2022, 43: e20210057.

[12] LOPES L O, COSTA D M, TIPPLE A V, et al. Complex design of surgical instruments as barrier for cleaning effectiveness, favouring biofilm formation[J]. J Hosp Infect, 2019, 103(1): e53-e60.

[13] COSTA D M, LOPES L K O, VICKERY K, et al. Reprocessing safety issues associated with complex-design orthopaedic loaned surgical instruments and implants[J]. Injury, 2018, 49(11): 2005-2012.

[14] ZHANG Y Q, LIU B, TONG Z Y. Adenosine triphosphate (ATP) bioluminescence-based strategies for monitoring atmospheric bioaerosols[J]. J Air Waste Manag Assoc, 2022, 72(12): 1327-1340.

[15] LIU S T, ZHAO J B, GUO Y L, et al. Application of ATP-based bioluminescence technology in bacterial detection: a review[J]. Analyst, 2023, 148(15): 3452-3459.

[16] RODRIGUEZ J A, HOOPER G. Adenosine triphosphate-bioluminescence technology as an adjunct tool to validate cleanliness of surgical instruments[J]. AORN J, 2019, 110(6): 596-604.

[17] LI Y, LU Y, CAI R, et al. Monitoring the cleanliness of reusable surgical instruments in central sterile supply department by adenosine triphosphate method[J]. J AOAC Int, 2022, 105(3): 844-847.

[18] SMITH A, WINTER S, LAPPIN D, et al. Reducing the risk of iatrogenic Creutzfeldt-Jakob disease by improving the cleaning of neurosurgical instruments[J]. J Hosp Infect, 2018, 100(3): e70-e76.

[19] YANG L Y, XUN Q, XU J, et al. Application of the defect management improvement mode under Joint Commission International standard to improve the instrument cleaning and disinfection effect and management quality in the central sterile supply department: a randomized trial[J]. Ann Transl Med, 2022, 10(3): 137.

[20] ASSADIAN O, HARBARTH S, VOS M, et al. Practical recommendations for routine cleaning and disinfection procedures in healthcare institutions: a narrative review[J]. J Hosp Infect, 2021, 113: 104-114.

[21] OFSTEAD C L, HOPKINS K M. Sterilization central: the value of borescopes in detecting damage, soil, fluid, and foreign objects in flexible endoscopes[J]. Biomed Instrum Technol, 2020, 54(2): 146-152.

[22] OFSTEAD C L, SMART A G, HOPKINS K M, et al. The utility of lighted magnification and borescopes for visual inspection of flexible endoscopes[J]. Am J Infect Control, 2023, 51(1): 2-10.

[23] VEIGA-MALTA I. Preventing healthcare-associated infections by monitoring the cleanliness of medical devices and other critical points in a sterilization service[J]. Biomed Instrum Technol, 2016, 50(Suppl 3): 45-52.

[24] HERVÉ R C, HEDGES J, KEEVIL C W. Improved surveillance of surgical instruments reprocessing following the variant Creutzfeldt-Jakob disease crisis in England: findings from a three-year survey[J]. J Hosp Infect, 2021, 110: 15-25.

[25] CHEN A Q, ZOU X M, TAN Y H, et al. Multicenter comparative study of three “non-destructive” methods of detecting the cleanliness of the da Vinci surgical robotic instrument[J]. Gland Surg, 2021, 10(12): 3305-3313.

[26] BRONZATTI J G, DE SOUZA R Q, NIERO C V, et al. Evaluation of cleaning and sterilization of liposuction cannulas after intentional contamination with human fat, Mycobacterium abscessus subspecies bolletii, and Geobacillusstearothermophilus[J]. J Hosp Infect, 2023, 136: 8-13.

[27] RUTALA W A, WEBER D J. Risk of disease transmission to patients from “contaminated” surgical instruments and immediate use steam sterilization[J]. Am J Infect Contr, 2023, 51(11): A72-A81.