DOI: 10.11910/j.issn.2791-2043.2026.2.05

Innovative Application of a Synergistic ATP Bioluminescence Assay–Video-in-Video Visualization–Traceability System for Closed-Loop Management of the Central Sterile Supply Department

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ABSTRACT: Objective To investigate the effectiveness of the three-technology synergistic system integrating adenosine triphosphate (ATP) bioluminescence assay, video-in-video visualization inspection, and intelligent traceability in the closed-loop management of the Central Sterile Supply Department (CSSD), and to establish a new intelligent, end-to-end, and traceable model for instrument cleaning quality control. **Methods** Reusable surgical instruments processed by the CSSD of our hospital from July 2024 to June 2025 were included in this study. A synergistic management system integrating ATP rapid primary screening, video-in-video visualization inspection, and intelligent end-to-end traceability was established. A self-controlled before-and-after study design was employed, with instruments processed from July to December 2024 assigned to the pre-implementation group (n=12,560) and those processed from January to June 2025 assigned to the post-implementation group (n=18,920). Two groups were compared in terms of cleaning pass rate, detection rate of residues in cannulated instruments, quality issue traceability time, clinical department satisfaction with CSSD services, and healthcare-associated infection indicators. **Results** After implementation of the three-dimensional integrated technology, the overall instrument cleaning pass rate increased from 92.35% to 99.78% (χ^2=347.26, p<0.05); the pass rate of cannulated instruments increased from 88.17% to 99.69% (χ^2=298.51, p<0.05); the detection rate of biological/particulate residues in cannulated instruments decreased from 7.82% to 0.31% (χ^2=265.38, p<0.05); average time required for quality issue traceability was reduced from (45.2±6.8) min to (8.3±2.1) min (t=42.17, p< 0.05); and clinical department satisfaction scores increased from (91.6±3.2) to (98.9±1.1) (t=18.63, p<0.05). **Conclusion** The three-technology synergistic system integrating ATP bioluminescence assay, video-in-video visualization, and intelligent traceability enables closed-loop management of cleaning quality characterized by “rapid detection - precise verification - end-to-end traceability - continuous improvement”. It can significantly enhance the quality and safety management of sterile supply services, providing innovative technical support for the prevention and control of healthcare-associated infections.

KEY WORDS: Adenosine triphosphate (ATP) bioluminescence assay; Video-in-video visualization; Traceability system; Central Sterile Supply Department (CSSD); Closed-loop management; Cleaning quality

1 Introduction

The Central Sterile Supply Department (CSSD) is the core hospital department responsible for the reprocessing of reusable medical devices. It undertakes the collection, cleaning, disinfection, sterilization, and distribution of reusable instruments throughout the hospital. The quality of its operations is directly related to medical safety and the effectiveness of healthcare-associated infection prevention and control[1]. The WS 310—2016 Central Sterile Supply Department series of standards explicitly requires

that reusable instruments be cleaned to a standard of "no blood stains, no visible soil, and no residual tissue". Hidden areas, such as lumens, serrations, and joints, are identified as the key focus and major challenge of quality control[2].

With the rapid development of minimally invasive surgical techniques, sophisticated and structurally complex cannulated instruments, including laparoscopes, hysteroscopes, and minimally invasive orthopedic instruments, have been increasingly used in clinical practice. These instruments are characterized by complex structures, narrow lumens, and multiple joints. Conventional cleaning methods often fail to ensure adequate cleanliness of the inner lumen surfaces, making their reprocessing a high-risk area in healthcare-associated infection prevention and control[3]. Studies have shown that biofilm formation resulting from inadequate cleaning of cannulated instruments is one of the major causes of sterilization failure and healthcare-associated infection outbreaks[4]. Therefore, establishing a scientific, efficient, and traceable cleaning quality management system is of great importance for ensuring medical safety.

Currently, cleaning quality management in CSSDs in China has three major limitations. ① Although the adenosine triphosphate (ATP) bioluminescence assay is rapid and easy to perform, it can only reflect the overall bioburden level and cannot identify the specific location of residues within lumens or distinguish between organic and inorganic residues[5]; ② Video-in-video visualization inspection (using a fiberoptic endoscope) enables direct visualization of the interior of lumens; however, instrument-by-instrument inspection is relatively inefficient, lacks quantitative assessment criteria, and makes inspection images and data difficult to retain and trace[6]; ③ Intelligent traceability systems are generally limited to recording workflow steps and are disconnected from inspection data, making it difficult to achieve closed-loop management featuring "inspection - early warning - traceability - improvement"[7]. The use of any single technology has inherent limitations and cannot meet the clinical need for high-quality management of sophisticated and complex instruments.

This study innovatively established a three-technology synergistic system integrating ATP bioluminescence assay, video-in-video visualization, and intelligent traceability. By deeply integrating rapid quantitative detection, visualized detailed inspection, and full-process information-based traceability, the system aims to achieve closed-loop management featuring "automatic acquisition of inspection data, real-time early warning of abnormal findings, precise traceability of responsible workflow steps, and continuous quality improvement", thereby providing practical evidence for innovation in quality control technology for sterile supply.

2 Materials and methods

2.1 Study materials

A self-controlled before-and-after study was conducted using reusable surgical instruments reprocessed by the CSSD of our hospital between July 2024 and June 2025 as the study materials. The period from July to December 2024 was designated as the pre-implementation group (conventional quality control model), comprising 12,560 instruments, while the period from January to June 2025 was designated as the post-implementation group (three-technology synergistic quality control model), comprising 18, 920 instruments. During the study period, the number of minimally invasive surgical procedures performed at our hospital continued to increase. In the first half of 2025, the surgical volume was approximately 38% higher than that during the corresponding period in 2024. In addition, the monitoring scope for precision cannulated instruments was expanded after implementation, resulting in a larger sample size in the post-implementation group. No statistically significant differences were observed between the two groups in terms of instrument composition, contamination grade, or reprocessing procedures, indicating that the groups were comparable.

The study materials included specialty instruments used in general surgery, orthopedics, obstetrics and gynecology, neurosurgery, and other clinical specialties, with particular emphasis on monitoring

cannulated instruments and precision articulated instruments. The two groups were comparable with respect to instrument type, contamination grade, and reprocessing procedures.

2.2 Equipment and materials

2.2.1 ATP bioluminescence assay system

An ATP bioluminescence analyzer (Chuangxin Shiji) and dedicated sampling swabs were used. The system operates on the luciferin–luciferase bioluminescence reaction principle. Measurements are completed within 15 s, and the results are displayed directly as numerical relative light unit (RLU) values, enabling rapid assessment.

2.2.2 Video-in-video visualization inspection system

A cannulated instrument visualization workstation (Chuangxin Shiji) was used. The inspection probe features a lens and LED illumination system with a diameter of 1.9 mm (±0.1 mm) and is optionally available with a 1.0 mm (±0.1 mm) ultra-fine lens. The probe has a working length of 80 cm (customizable), making it suitable for internal inspection of various types of cannulated instruments. The system is equipped with a high-definition imaging system, enabling real-time visualization and storage of images of the lumen interior.

2.2.3 CSSD intelligent traceability system V2.0

An in-house developed CSSD intelligent traceability system V2.0 was used. The system supports dual QR code/RFID identification, automatic data acquisition, real-time abnormality alerts, end-to-end traceability, and report generation and analysis. The system covers all stages of the reprocessing workflow, including collection, cleaning, disinfection, packaging, sterilization, storage, distribution, clinical use, and return collection, enabling full lifecycle management of instruments.

2.2.4 Other equipment and materials

Other materials included standard cleaning and disinfection equipment (Belimed automatic washer disinfector), medical multiple enzyme detergent (Micro-Scientific, USA), and packaging materials (medical crepe paper and nonwoven fabric), all of which complied with the requirements of the WS 310 series of standards.

2.3 Construction of the integrated technology linkage system

2.3.1 Technology linkage workflow logic

A mechanism integrating “three-step testing, data interconnection, and closed-loop quality control” was established:

2.3.1.1 ATP rapid primary screening: After cleaning, instruments first undergo ATP bioluminescence assay, with samples collected from instrument surfaces and lumen openings for analysis. A graded evaluation criterion is applied: RLU >20 is directly determined as non-conforming, and the instruments are returned for re-cleaning; instruments with 10<RLU⩽20 proceed to the video-in-video precision verification stage; and instruments with RLU⩽10 are directly determined as qualified by ATP testing. ATP rapid primary screening enables high-throughput, rapid screening of instrument batches, thereby improving inspection efficiency.

2.3.1.2 Video-in-video precision verification: For cannulated instruments and precision articulated instruments with suspicious ATP test results (10<RLU⩽20), the video-in-video system is used for visual precision verification. The inspection focuses on concealed areas, including inner lumen walls, joint contact surfaces, and serrated areas, to identify any residual contaminants, stains, or rust spots. Video-in-video precision verification compensates for the limitations of ATP testing, which may be unable to visually identify contamination sources or accurately locate defects, enabling precise identification and localization of problems.

2.3.1.3 Closed-loop traceability system: Data, including ATP test values, Video-in-video inspection images, inspection time, operator information, instrument IDs, and cleaning parameters, are automatically synchronized to the traceability system to establish a complete electronic record. Abnormal data trigger real-time alerts, automatic lockout, and precise root-cause traceability. This enables rapid identification of quality issues and accountability tracking, and provides data support for continuous improvement.

2.3.2 System integration and process optimization

2.3.2.1 Data interface development: Data interfaces

were independently developed to enable seamless interoperability among ATP detectors, video-in-video equipment, and the traceability system. Test data and images are automatically uploaded and associated with a single click, to eliminate errors from manual data entry and ensure data authenticity, accuracy, and integrity.

2.3.2.2 End-to-end closed-loop traceability nodes: An end-to-end closed-loop traceability workflow was established, covering "collection → sorting → cleaning → ATP testing → video-in-video precision inspection → packaging → sterilization → storage → distribution → use → collection". Each process node was linked through barcode scanning, with operator information, operation time, equipment parameters, and other relevant data recorded throughout the process, enabling end-to-end traceability across the entire lifecycle of instruments.

2.3.2.3 Intelligent alert rules: Multi-level intelligent alert rules are established, including alerts for excessive ATP levels, abnormal video-in-video inspection results, non-compliant cleaning parameters, sterilization failures, and approaching expiration dates. Automatically, the system pushes alerts to responsible personnel, enabling a proactive management model where issues are automatically assigned to designated staff, thereby improving the response speed to quality issues.

2.3.3 Quality standards and personnel training management

2.3.3.1 Standardized criteria: Unified inspection acceptance criteria were established: ① ATP acceptance criterion: RLU≤20; ② Video-in-video inspection criteria: the inner lumen walls shall have no visually detectable residues, particulates, stains, or rust spots; joints shall move smoothly with proper alignment and engagement.

2.3.3.2 Personnel training: A systematic training program was established, with targeted training provided on ATP operation procedures, Video-in-video inspection interpretation criteria, and traceability system operation workflows. All operators are required to pass competency assessments before being authorized to perform operations. Monthly refresher training and quarterly skill assessments are conducted to continuously improve operators' technical proficiency and inspection interpretation capabilities. During the study period, the operator team remained stable, and all core operators had more than three years of CSSD work experience.

2.4 Observation indicators

2.4.1 Instrument cleaning pass rate: Blinded sampling inspection was performed to calculate the overall instrument cleaning pass rate and the cleaning pass rate of cannulated instruments according to WS 310.3.

2.4.2 Detection rate of residues in cannulated instruments: A combined video-in-video inspection and ATP testing assessment was used to determine the detection rate of biological/particulate residues in cannulated instruments.

2.4.3 Quality issue traceability time: The average time required from the identification of a quality issue to the determination of the responsible process step, operator, and root cause was recorded.

2.4.4 Clinical department satisfaction with CSSD services: A self-developed satisfaction questionnaire (100-point scale) was used. The questionnaire was designed with reference to the Guidelines for Quality Evaluation of Hospital Central Sterile Supply Department and included dimensions such as instrument cleanliness, supply timeliness, and packaging integrity. A preliminary survey showed that the questionnaire had a Cronbach's α coefficient of 0.87, indicating good internal consistency. Satisfaction with sterile supply services among operating rooms and clinical departments was assessed.

2.4.5 Healthcare-associated infection indicators: Changes in healthcare-associated infection indicators, including surgical site infection rates and instrument-associated infection rates, were monitored before and after implementation.

2.5 Statistical methods

Data were analyzed using SPSS version 22.0 statistical software. Categorical data were expressed as percentages (%), and between-group comparisons were performed using the χ^2 test. Continuous variables that followed a normal distribution according to the normality test were expressed as mean ± stan-

dard deviation (x±s), and between-group comparisons were performed using the independent-samples *t*-test. A *p*-value of less than 0.05 was considered statistically significant.

3 Results

3.1 Comparison of cleaning quality indicators

After implementation of the integrated technology linkage system, the overall instrument cleaning pass rate and the cleaning pass rate of cannulated instruments increased significantly, while the residue detection rate decreased substantially. All differences were statistically significant (all $p<0.05$), as shown in Table 1.

3.2 Comparison of management efficiency and satisfaction indicators

After implementation of the integrated technology linkage system, the quality issue traceability time was significantly reduced, and the clinical department's satisfaction with CSSD services was significantly increased. All differences were statistically significant (all $p<0.05$), as shown in Table 2.

3.3 Healthcare-associated infection indicators

After implementation of the integrated technology linkage system, the surgical site infection rate decreased from 0.85% to 0.32%, and the instrument-associated infection rate decreased from 0.52% to 0.18%, showing a downward trend. However, due to the limited number of surgical cases during the study's observation period and the small number of healthcare-associated infection events, the difference was not statistically significant ($p>0.05$). Further observation with an expanded sample size is needed.

4 Discussion

4.1 Mechanism of complementary advantages of the three-technology synergistic system

Conventional CSSD cleaning quality control largely relies on single detection methods, which have inherent limitations. As a rapid screening approach, the ATP bioluminescence assay has been widely applied in CSSDs worldwide[8]. Studies have shown that ATP testing can provide a quantitative assessment of cleaning quality within minutes and is suitable for high-throughput screening. However, there exists a limitation that it only reflects the overall biological burden, cannot distinguish between organic and inorganic residues, and cannot identify the specific locations of residual contamination[9]. In this study, ATP rapid primary screening enabled early identification of obviously non-conforming instruments, preventing them from proceeding to subsequent processing steps and improving quality control efficiency.

The video-in-video visualization inspection technology is an emerging method for detecting cannulated instruments, enabling direct visualization of internal lumen surfaces[10]. Liu Jieying et al.[6] reported that the failure rate of cleaning cannulated instruments detected by borescope inspection was 20.5%, which was higher than the 5.5% detected by the airgun blowing method. Su Yingying et al.[11] also demonstrated that electronic projection otoscopes could improve the detection rate of inadequate cleaning in instrument lumens. In this study, video-in-video precision verification provided secondary validation for instruments with suspicious

Table 1 Comparison of Cleaning Quality Indicators Before and After Implementation

Indicator	Before implementation (n=12,560)	After implementation (n=18,920)	χ^2/t value	p-value
Overall instrument cleaning pass rate	92. 35%(11600/12560)	99. 78%(18879/18920)	347. 26	<0. 05
Cleaning pass rate of cannulated instruments	88. 17%(3410/3868)	99. 69%(5812/5830)	298. 51	<0. 05
Detection rate of residues in cannulated instruments	7. 82%(303/3868)	0. 31%(18/5830)	265. 38	<0. 05

Table 2 Comparison of Management Efficiency and Satisfaction Indicators Before and After Implementation

Indicator	Before implementation	After implementation	t value	p-value
Average time required for quality issue traceability (min)	45. 2±6. 8	8. 3±2. 1	42. 17	<0. 05
Clinical department satisfaction with CSSD services (score)	91. 6±3. 2	98. 9±1. 1	18. 63	<0. 05

ATP primary screening results, focusing on concealed areas such as inner lumen walls and joints. It compensated for the limitations of ATP testing, including its inability to visually identify contamination or accurately locate residues, thereby enabling precise localization and qualitative assessment.

The intelligent traceability system provides essential technical support for closed-loop management in sterile supply services[12]. Shi Xiaoyi et al.[7] demonstrated that establishing a full-process quality control system enables traceability and status tracking of sterilized surgical instruments, providing data support for precision infection control. However, conventional traceability systems are often limited to process documentation and remain disconnected from inspection data, making it difficult to achieve true closed-loop management[13]. In this study, ATP test data and Video-in-video inspection images were integrated with the traceability system through data interface development, enabling closed-loop management characterized by automatic data acquisition, full-process audit trails, precise root-cause traceability, and continuous improvement.

The three components complement each other's advantages, forming a quality control chain of "rapid screening → precision verification → end-to-end traceability → continuous improvement". This integrated approach helps address the challenges associated with cleaning quality control of complex and precision instruments.

4.2 Impact of the three-technology synergistic system on quality and safety control

The results of this study showed that after implementation of the three-technology synergistic system, the overall instrument cleaning pass rate increased to 99.78%, the cleaning pass rate of cannulated instruments increased to 99.69%, and the residue detection rate in cannulated instruments decreased to 0.31%. The quality control outcomes were significantly improved compared with those before implementation (all $p<0.05$). The value of this approach is mainly reflected in the following four aspects:

By shifting quality control checkpoints upstream, this approach breaks the conventional passive management model of post-process random inspection and establishes a proactive prevention and control mechanism. ATP rapid primary screening enables early identification of issues immediately after cleaning, allowing timely interception of non-conforming instruments and preventing them from entering subsequent processes such as packaging and sterilization, thereby reducing medical safety risks at the source. This "in-process intervention" model provides more effective control of quality risks compared with conventional "post-process random inspection".

In terms of establishing a dual quality control mechanism, the ATP bioluminescence assay provides a quantitative assessment, while video-in-video visual inspection enables precise localization. The two methods complement and validate each other, helping eliminate quality control blind spots in concealed areas such as lumens and joints. ATP testing provides objective quantitative data, while video-in-video inspection offers direct visual evidence. Together, they provide dual assurance for precise control of cleaning quality. This integrated "quantitative + qualitative" quality control model enables a more comprehensive evaluation of cleaning performance than either method alone.

In terms of enhancing traceability management efficiency, through the three-technology synergistic system, inspection data and operational information are associated with the traceability system through one-click linkage. The average time required for quality issue traceability was reduced from 45.2 min to 8.3 min, enabling rapid identification of the responsible process step, operator, and root cause, thereby improving management efficiency. Li Xiaopeng et al.[14] also demonstrated that informatized closed-loop management can reduce errors in sterile item distribution and improve work efficiency. Rapid traceability not only enhances management efficiency but also enables prompt identification of problematic instruments and timely implementation of control measures in the event of a healthcare-associated infection, reducing the risk of infection transmission.

In terms of continuous quality improvement, the traceability system automatically aggregates and

analyzes end-to-end process data and generates multi-dimensional quality control reports. It identifies weak points (such as inadequate cleaning of specific instrument types, non-standard operations during particular shifts, or declining equipment performance), providing data support for PDCA cycle optimization and driving continuous improvement in CSSD quality control. Compared with conventional experience-based management, this data-driven management model is more targeted and effective.

4.3 Application value and dissemination prospects

4.3.1 Integrated technology application

This study integrated ATP bioluminescence assay, video-in-video visual inspection, and an intelligent traceability system to establish an intelligent closed-loop management system featuring "rapid detection → precision verification → end-to-end traceability → continuous improvement". The three components were integrated through data interfaces, creating synergistic effects. To date, no relevant reports on the deep integration of these three technologies have been identified in China. This study provides a new technical approach for quality control in sterile supply services.

4.3.2 Standard operating procedure

A standard operating procedure (SOP) was established, consisting of "ATP primary screening → video-in-video precision verification → system traceability → alert response and corrective actions". The SOP defines the operational requirements, evaluation criteria, and coordination mechanisms for each stage. It is replicable and can serve as a reference for CSSDs in hospitals at different levels.

4.3.3 Optimization of the management model

The implementation has facilitated a transition from manual experience-based management to a management model characterized by "data-driven decision-making, intelligent early warning, and end-to-end controllability". Management decisions have shifted from experience-dependent judgments to data-based decision-making; problem response has evolved from passive handling to proactive early warning; and quality improvement has progressed from generalized corrective actions to targeted interventions. This transformation helps enhance the scientific and refined management capabilities of the CSSD.

This technology is applicable to CSSDs at all levels of hospitals, particularly tertiary hospitals performing minimally invasive and complex precision surgeries, where it can help ensure medical safety and reduce the risk of healthcare-associated infections. With the development of regional sterile supply centers, the technology can be further extended to regional centralized supply models, providing technical support for achieving standardized and consistent quality management across regions.

4.4 Limitations and prospects

This study has several limitations: ① A self-controlled before-and-after study design was adopted. Although confounding factors such as personnel and equipment were controlled as much as possible, the influence of other unknown confounding factors cannot be completely excluded, limiting the strength of causal inference; ② The video-in-video inspection equipment has a relatively high cost, and the ultrathin endoscopes require standardized maintenance, which may restrict its broader adoption in primary-level hospitals; ③ Certain ultra-small lumens (<0.5 mm) remain challenging to inspect, necessitating further development of more refined inspection technologies; ④ This was a single-center study with a limited sample size, and the generalizability of the findings requires further validation through multicenter studies.

Future research directions can include: integrating artificial intelligence-based image recognition technologies to enable automated interpretation of endoscopic inspection results, thereby improving detection efficiency and objectivity; integrating with hospital HIS/EMR systems to establish full-chain traceability of "instruments-patients-infections", providing support for precision prevention and control of healthcare-associated infections; developing a regional CSSD quality control platform to enable data sharing and standardized quality management, thereby improving the overall quality of sterile supply services across regions; and conducting health economics evaluations to assess the cost-effectiveness

of the technology and provide an economic basis for its wider adoption.

5 Conclusion

The three-technology synergistic system integrating ATP bioluminescence assay, video-in-video visualization, and intelligent traceability represents a valuable exploration of closed-loop management in CSSD. By integrating rapid quantitative detection, visualized precision verification, and end-to-end digital traceability, this approach helps improve instrument cleaning quality, management efficiency, and healthcare-associated infection prevention and control. It supports the achievement of the management objectives of "controllable quality, traceable processes, clear accountability, and continuous improvement" and provides a reliable solution for modernizing quality management in hospital CSSDs.

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