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RESEARCH

Fabrication and application of continuous douche for Da Vinci surgical robot arm

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Abstract

Background The use of robotic surgery in hospitals is becoming increasingly widespread.

Objective This research was performed to design a continuous douche for surgical robotic arm operated instruments and evaluate its use.

Methods A continuous irrigator was designed for robotic arm operated surgical instruments. A total of 240 recovered robotic-arm instruments were selected from the Disinfection Supply Center of our hospital. These were divided into two groups according to their recycling order, with single number instruments in the control group and even number instruments in the experimental group. Each group included 120 pieces. In the experimental group, continuous douching was used for perfusion and soaking, while control group instruments were infused and soaked using a 50 mL syringe. Data on cleaning quality, accuracy of perfusion tool injection volume, incidence of liquid reverse osmosis during injection and washing, and product satisfaction were collected for both groups.

Results The qualified manipulator cleaning rate and satisfaction with perfusion tools were higher in the experimental group than in the control group, and incidence of liquid reverse osmosis was lower in the experimental group than in the control group.

Conclusions The self-made continuous perfusion device improved the instrument cleaning efficacy of the robotic surgical arm, accuracy of injection volume, and product satisfaction.

Keywords Continuous lavage device · Surgical robotic arm · Da Vinci surgical system · Perfusion cleaning · Central sterile supply department

Introduction

Robotic surgical systems expand minimally invasive surgery capabilities by extending surgeons' hand and eye functionality in endoscopic surgeries, enabling them to perform surgical operations more accurately to microscopic levels [1, 2]. A robotic surgery system comprises an operating table, a 3D imaging system, and an intelligent robotic arm system [3–5]. An intelligent mechanical arm, as a key component, is a life-counting instrument with a service life of 10 uses before requiring reprocessing. This component is difficult to clean due to the absence of movable joints, and due to bioburden embedded in its joints and pores [6]. The Da Vinci Robot Manufacturer's Manual recommends cleaning methods requiring repeated perfusion and irrigation, with a recommended perfusion volume≥15 mL and perfusion pressure≥2 Bar. The price of mechanical arms is high ($3,000 to $5,000), resulting in a scarcity of spare

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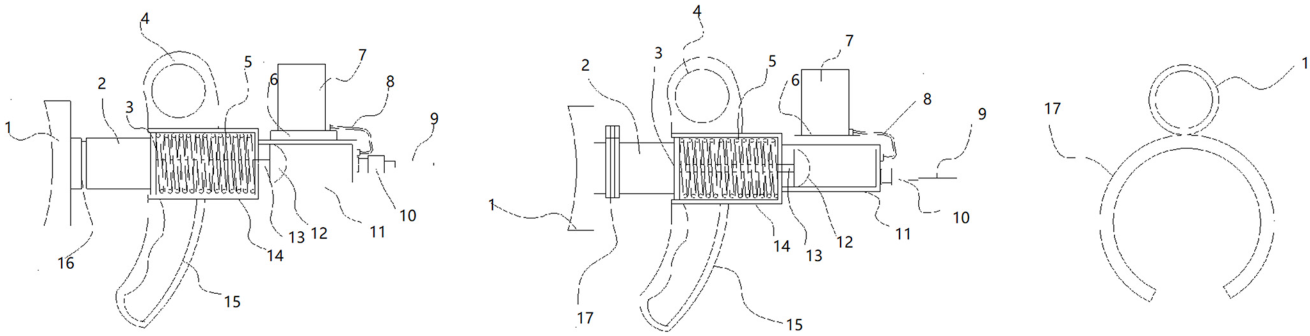

Fig. 1 Structure diagram of special continuous douche.1, Push the handle; 2, the putter; 3. Slide block; 4, on the handle; 5. Spring; 6. Installation department; 7. Cleaning agent container; 8. Hose; 9. Injection tube; 10. Luer connector; 11, piston cylinder; 12, piston head; 13. Piston rod; 14. Install sleeve; 15. Lower handle; 16, groove; 17, clamp ring; 18. Hand-held section

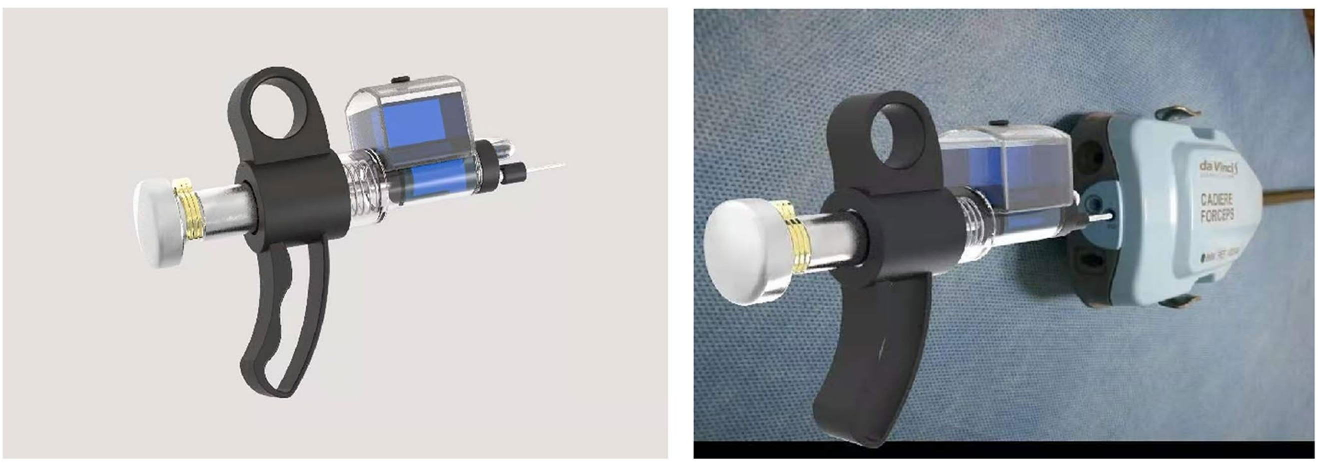

Fig. 2 The physical structure of continuous douche

mechanical arms, which amplifies patient safety risks due to utilization of equipment processed in a short operation cycle [7–10]. Qualified perfusion cleaning is thus an important step in ensuring high quality cleaning of robotic arm instruments. Appropriate perfusion cleaning methods can improve robot arm cleaning efficiency, thereby enhancing its turnover efficiency and ensuring patient safety. In 2021, our team designed a continuous douche device (hereinafter referred to as "special continuous douche device," utility model patent authorization: ZL2020209831374) specially for Da Vinci surgical robot arms, which was put into clinical use in April 2021 and has achieved excellent application efficacy.

Materials and methods

Study samples

Initially, a total of 440 Da Vinci robot arm instruments were recovered from the disinfection supply center of our hospital. We selected subject instruments according to the following inclusion criteria: ① The device was complete and functional; ② Operation time was > 3 h, obvious blood stains were observed on the instrument's surface after operation, and an ATP value of more than 10,000 was obtained; ③ All selected instruments had been used in urological or general surgeries. The exclusion criteria were: ① incomplete or not fully functional instrument; ② The device had been used > 10 times; ③ Foreign robotic surgical arm instruments. Only 240 suitable instruments were obtained. These were divided into a control group ($n = 120$) and an experimental group ($n = 120$), with single use instruments in the control group and even number use instruments in the experimental group, according to their recycling order.

Guidance for special continuous douche use

The structure and working principles of the special continuous douche device are illustrated in Figs. 1 and 2. The device consists of a push handle (1), push rod (2), slider (3), upper handle (4), spring (5), mounting part (6), cleaning agent container (7), hose (8), injection tube (9), Luer connector (10), piston barrel (11), piston head (12), piston rod

(13), mounting sleeve (14), lower handle (15), groove (16), clamp ring (17), and handheld Sect. (18). During operation, the user pushes the handle (1), causing the push rod (2) to drive the piston head (12) within the piston barrel (11), thereby compressing and expelling the cleaning agent. When the spring (5) resets the push rod, the second check valve opens, and the first check valve closes, allowing cleaning agent to flow from the cleaning agent container (7) into the piston barrel via the hose (8). When the push rod is pressed again, the first check valve opens while the second closes, and the cleaning agent is injected through the Luer connector (10) into the robotic arm. The volume of cleaning agent per injection is controlled by adjusting the number of clamp rings (17) on the push rod, which limits the stroke length. This device enables continuous perfusion, eliminating the need for repeated syringe refills and significantly improving cleaning efficiency. The design achieves a constant cleaning pressure of up to 2 Bar, generating a strong and uniform flow that effectively removes contaminants from the robotic arm's internal surfaces. The Luer connector ensures a secure fit with the robotic arm's interface, reducing backflow and minimizing environmental contamination. Ergonomic features, such as the upper and lower handles (4, 15), enhance grip stability and ease of operation, while the spring-reset mechanism reduces user effort. These design improvements increase operator satisfaction and significantly enhance the cleaning quality and efficiency compared to traditional 50 mL syringes. The device ensures a higher pass rate for cleaning robotic surgical instruments, particularly in challenging internal areas, thereby meeting stringent surgical hygiene standards.

Cleaning methods

①Pretreatment: The recovered manipulator was washed with running water for 2 min, then the obvious blood stains and the stains on the surface of the instrument were scrubbed away using a low fiber cloth. Perfusion and soaking: A 1:200 solution of Kebejie neutral multi-enzyme cleaning agent was prepared. For the experimental group, the Kebejie cleaning agent was poured into a dedicated continuous perfusion device cleaning agent container attached to the push rod, and the Luer adapter of the flushing device was inserted directly into the main flushing port of the robotic arm. For the control group, the prepared multi-enzyme cleaning agent was placed into a 50 mL syringe, and its adapter was inserted directly into the robotic arm's main flushing port. The push rod of the flushing device was pushed until the multi-enzyme cleaning agent emerged from the robotic arm's disk gap. Flushing was repeated 3 times, and the same method was performed to perfuse the secondary aperture. The robotic arm was then immediately completely immersed in multi-enzyme cleaning agent for 30 min. ③ Scrubbing: The outer surface and end of the instrument was thoroughly scrubbed, moving the wrist of the instrument during scrubbing the until all surface area has been scrubbed. ④ Ultrasonic cleaning: In the experimental group, 15 mL of the multi-enzyme cleaning agent was poured into the main flushing port using the dedicated continuous perfusion device. In the control group, 15 mL of multi-enzyme cleaning agent was injected into the main flushing port using a 50 mL syringe. The instrument was then completely immersed in cleaning agent, and ultrasonic cleaning was performed for 15 min. Perfusion and flushing: In the experimental group, the cleaning agent chamber of the perfusion device was closed, flushed with softened water, and used to perfuse and flush the robotic arm. In the control group, softened water from a 50 mL syringe was extruded to brush, perfuse and flush the robotic arm. During flushing, the end head was depressed and the instrument's wrist was rotated until the water ran clear. A 10x magnifying glass was used to check cleanliness. Injection was repeated with flushing and scrubbing as necessary. Terminal flushing was performed once and twice for at least 20 s each until the water emerged clear. ⑥ Drying: Surface moisture was dried with an air gun, then arms were placed in a negative pressure drying cabinet for a 55°C, 25-minute drying program. Disinfection: Gloves were replaced and robotic arms were injected and surface disinfected with 75% ethanol.

Quality control

Six nurses participated in the instrument cleaning experiment in this study, with titles above supervisor nurse, bachelor's degree, and more than three years of working experience in processing robot instruments in disinfection supply centers. The head nurse and quality control team leader were jointly considered responsible for experimental implementation of mechanical arm instrument cleaning and marking of processing time. Two quality control nurses who had worked in the disinfection supply center for more than 5 years were responsible for cleaning, quality monitoring, and data sorting.

Observation indicators and efficacy evaluation

Evaluation criteria for qualified cleaning assessment: ① Visual inspection combined with magnifying glass detection method: The surface of the mechanical arm instrument is clean under magnification and illumination with a 10X ambient light source. If no residual material, such as blood, scale, or rust stains are found, the instrument is qualified; otherwise, it is unqualified [11]. Adenosine triphosphate (ATP) biofluorescence detection method: a 3 M Clean-Trace

ATP NG3 ATP surface sampling rod was rubbed at least five times on the occlusal surface of the end of the robotic arm instrument, the gap of the wrist, and the disk surface, with a sampling area > $5cm^2$. The sampling rod was then placed into the sampling tube with the sampling part of the sampling rod in full contact with the cracking solution. The rod was oscillated evenly for at least 5 s, then placed in the test-tube chamber of the ATP detector for reading. ATP values ≤ 2000 RLU are qualified [12, 13], and values > 2000 RLU are unqualified.③ Eluent cleaning quality test: Eluent was extracted using aseptic operation methods. A sterile 50 mL glass syringe was used to push the eluent from the primary and secondary rinses into the cleaned and dried mechanical arm, and a sterile bowl was used to collect the eluent after rinsing. A 3 M Clean-Trace ATP NG3 ATP water-quality sampling rod was used for sampling. The rod was placed in a sample tube containing lysate and oscillated for at least 5 s before being placed in a detector for reading. ATP values ≤ 200 RLU are qualified. Values > 200 are unqualified. Additional evaluation indicators: ① Constant perfusion dose of the perfusion tool: the perfusion measurement is controlled by the clamp to achieve constant fluid pressure ≥ 2 Bar. ② Incidence of liquid reverse osmosis during perfusion: The incidence of liquid reverse osmosis during operation of the two perfusion tools was compared. Regurgitation rate = cases of liquid regurgitation ÷ 120 × 100%. ③ Product satisfaction survey: A questionnaire on the application efficacy and application experience of two kinds of perfusion tools in the injection and washing of robot arm, including the overall structure, mechanical and electrical configuration, working reliability, track biting, injection feeling, injection and washing stability, etc., was distributed and responses were scored on a scale of 0-100. The results were evaluated as follows: Satisfied (90–100 points), somewhat satisfied (80–89 points), minimally satisfied (60–79 points), somewhat dissatisfied (40–59 points), dissatisfied (0–39 points). A total of 240 questionnaires were sent out, with 237 completed and returned for an effective recovery rate of 98.75%.

Statistical methods

Statistical analyses were performed using SPSS version 19.0. 3. Measurement data were expressed as means ± standard deviations and analyzed by t test. Statistical data are presented as numbers of cases and percentages. χ^2 analysis was used for comparisons between groups. All statistical tests were two-sided, and statistical significance was set at $P < 0.05$.

Results

Structure of the special continuous douche device

The special continuous douche includes a push handle, push rod, slider, upper handle, spring, mounting base, cleaning agent container, hose, injection pipe, Luer joint, piston barrel, piston head, piston rod, mounting sleeve, lower handle, groove, clasp, and hand.

A mounting sleeve was connected to the end of the piston barrel, and a slide block and spring were installed in the sleeve. The slider was connected to a push rod and the piston head through a piston rod. The spring surrounds the piston rod, with one end pressing on the bottom of the mounting sleeve and the other end pressing on the slide block. The head of the piston cylinder was equipped with a cleaning agent outlet and cleaning agent inlet, and the piston cylinder sidewall was equipped with a mounting base and cleaning agent container. The cleaner container was connected to the cleaner inlet via a hose. The cleaning agent outlet was connected to the injection pipe through a Luer joint. The first and second check valves were installed at the cleaning agent outlet and inlet, respectively.

For convenience, the end of the push rod was provided with a push handle, the upper and lower handles were installed on the upper and lower sides of the mounting sleeve, and the handles were provided with operating holes for the fingers to reach. The continuous cleaner also includes a plurality of detachable clappers provided with grooves in the corresponding insertion position as shown in Figs. 1 and 2.

The comparison of general data between two groups

We initially collected information comparing duration of device use, operation time, waiting for processing time, and degree of instrument contamination between the two groups. As shown in Table 1, compared with the control group, there were no significant differences in use time, operation duration, processing wait time, degree of instrument contamination, or other general data within the experimental group ($P > 0.05$).

Table 1 Comparison of general data between the two robotic arm groups ($\bar{x} \pm s$)

Item	experimental group (n = 120)	control group (n = 120)	t	P
Number of instrument uses	5.13 ± 2.76	4.81 ± 2.17	0.31	0.18
operation time (h)	3.59 ± 0.71	3.83 ± 0.32	0.36	0.92
Processing wait time (h)	0.40 ± 0.18	0.39 ± 0.21	0.91	0.80
ATP (RLU)	194,000 ± 35,000	196,000 ± 26,000	1.94	0.79

Table 2 Comparison of cleaning quality between the two groups of robotic arms

Group	Number of detected pieces	Instrument surface cleaning pass rate by visual inspection [Example (percentage, %)]	ATP method detection device ends, plates cleaning pass rate [Example (percentage, %)]	Eluent method to detect the inner wall cleaning qualification rate of the instrument shaft [example (percentage, %)]
experimental group	120	117(97.5)	111(92.5)	105(87.5)
control group	120	101(84.2)	94(78.3)	87(72.5)
X^2		12.81	10.588	8.438
P		<0.01	<0.01	<0.01

Table 3 Comparison of additional evaluation indices between the two groups of perfusion tools

Group	Detection cases	Perfusion pressure constancy [Example (percentage, %)]	Incidence of fluid reflux [Example (percentage, %)]	Product satisfaction (%)
Innovative toolset	120	120(100)	5(4.2)	88.36±2.95
50 mL syringe set	120	94(78.3)	21(17.5)	79.8±2.23
Statistical values		29.159[a)]	9.622[a)]	12.03[b)]
P		<0.01	<0.01	<0.01

a represents the χ^2 value; b represents the *t* value

Comparison of cleaning quality between the two groups

Evaluation of the cleaning qualification rate indicators assesses whether product cleanliness meets required standards, thereby safeguarding product quality. We thus evaluated the differences in surface visual inspection, instrument end and disk ATP testing, and instrument shaft internal wall cleaning quality between the two sets of robotic arm instruments. The values of these indicators were significantly higher in the experimental group than those in the control group. ($P<0.01$; Table 2).

Comparison of additional evaluation indices between the two groups of perfusion tools

Statistically significant differences between groups were observed in injection volume accuracy, incidence of liquid reverse osmosis during injection and washing, and product satisfaction ($P<0.01$), as shown in Table 3.

Discussion

A robotic surgical system is a very complex surgical instrument with a complicated lumen and internal mechanical structure, making it challenging to reuse the instrument [14–16]. Thorough cleaning of robotic instruments is necessary to ensure effective sterilization and meet fundamental requirements of safe operation. As the core component of the surgical system, the mechanical arm should minimize its impact on its function during the cleaning and disinfection processes after each operation to ensure a continuous high-precision level during operations [17, 18]. However, it is difficult to achieve thorough cleaning by simple manual cleaning alone, and cleaning quality cannot be guaranteed because of the special structure of the robot arm, with alveoli, pores, and joints that cannot be split [19]. Junjun et al. [20] reported that the qualifying cleaning rate for a mechanical arm is 86.67%. They found that the sewage washed through the flushing port flowed back to the joints and gaps of the robot arm, and proper cleaning tools were not available during the cleaning process.

The cleaning process for robotic arm instruments includes multiple irrigation procedures. Currently, 50 mL syringes are used in most hospitals to perform perfusion and irrigation operations. Disadvantages of this method include the following: ① The syringe can only inject the cleaning agent into the mechanical arm once after absorbing it, and the volume of each injection is finite and fixed. The pressure generated during perfusion cannot reach 2 bar and complete rinsing cannot be achieved, probably leaving bioburden and cleaning agent in the inner cavity of the mechanical arm. ③ The injection head of the 50 mL syringe does not match the irrigation port of the mechanical arm, resulting in back seepage of cleaning agent and bioburden, threatening the safety of the operator and polluting the surrounding environment.

Comparison with other robotic arm cleaning systems

Several robotic arm cleaning systems and methods are currently used, each with distinct advantages and limitations. In comparison to traditional syringe-based methods, our special continuous douche device provides a significant improvement in cleaning quality. The continuous perfusion system features a metering clamp that precisely controls the perfusion rate to maintain a constant fluid pressure, ensuring uniform fluid flow throughout the robotic arm's internal cavity. This design helps prevent residual pollutants from re-entering the cavity and allows for more effective cleaning compared to syringe-based methods, where pressure and volume limitations often lead to suboptimal cleaning performance. Our device achieved a cleaning qualification rate of 87.5% for the inner wall of the instrument shaft, while the traditional syringe method only reached 72.5%. Moreover, the special continuous douche demonstrated higher cleaning qualification rates for the instrument surface and end/disk cleaning compared to the control group (Table 2), reinforcing its superiority in cleaning efficiency.

Existing robotic cleaning systems, such as automated robotic arm washers, often rely on fixed cleaning programs that are rigid in terms of cleaning duration, pressure, and cleaning agent flow. While these systems can achieve higher consistency in cleaning compared to manual methods, they are often bulky, complex, and require substantial maintenance. By contrast, our special continuous douche offers a more adaptable and cost-effective solution, with a design that is both user-friendly and ergonomic. The device's compatibility with various flush sizes, combined with its efficient one-way valve system, significantly reduces the risk of cleaning agent backflow and environmental contamination. This design ensures that cleaning agents are continuously delivered into the robotic arm, improving cleaning effectiveness and operator safety.

The special continuous Douche enhances Work Efficiency

The time and labor-intensive nature of syringe-based cleaning methods can also be a limitation. The 50 mL syringe requires multiple insertions and removals during the cleaning process, making it not only time-consuming but also less efficient. The special continuous perfusion device used in this study eliminates this inefficiency by enabling continuous irrigation with structural and functional improvements. The sleeve spring and piston reset design allow the piston to automatically reset after dispensing the cleaning agent, while the one-way valve ensures a continuous and unidirectional flow of cleaning agent. These features not only save time and improve operational convenience but also enhance the overall efficiency of the cleaning process.

The ergonomic design of the special continuous douche further contributes to work efficiency. Its large, wrench-compatible design enhances the stability of the device during use, making it more comfortable and reducing operator fatigue. The Luer joint design ensures a better fit with the robotic arm's irrigation port, reducing the risk of back seepage of fluids and subsequent contamination. As a result, operator satisfaction with the special continuous douche increased by 8.56% compared to traditional cleaning methods (Table 3), highlighting the device's efficiency and user-friendly design.

Future directions and potential for broader application

While the special continuous douche offers clear improvements over traditional syringe-based methods and other robotic cleaning systems, future studies should focus on optimizing its design further, particularly in terms of pressure control and fluid dynamics, to enhance cleaning performance in more complex robotic systems. Additionally, exploring the integration of quantitative measures, such as microbial counts or residue analysis, could provide a more comprehensive evaluation of cleaning efficacy. Expanding the application of this cleaning system to different types of robotic surgical systems and instruments could offer significant advantages in terms of both cleaning quality and operational efficiency.

Limitations

This study has several limitations. First, while the cleaning effectiveness was evaluated, the long-term impact on robotic arm function was not assessed. Additionally, the sample size was small, and a direct comparison with other automated cleaning systems was not made, which limits the generalizability of the findings. Microbial or residue analysis was also not included, which would provide a more comprehensive measure of cleaning efficacy. Moreover, the study did not explore factors like user experience or operator fatigue, which could affect the device's practical use. Finally, the lack of direct consultation with the robotic arm manufacturer means that future research should involve manufacturers to ensure compatibility and adherence to recommended maintenance guidelines.

Summary

In summary, the special continuous douche offers a novel and user-friendly design that enables continuous irrigation. The device is reusable, which helps reduce consumable usage and associated costs. Compared to traditional syringe-based perfusion and irrigation methods, it enhances cleaning efficiency and significantly improves robotic arm cleaning quality. The device demonstrated favorable application outcomes, with increased product satisfaction among users.

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Data availability The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Declarations

Competing interests The authors declare no competing interests.

Human Ethics and Consent to Participate declarations Not applicable.

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