DOI: 10.11910/j.issn.2791-2043.2024.2.05

Quality Detection method on cleaning quality of silicone tube in phacoemulsification

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ABSTRACT: Objective The present study intends to observe the cleaning effect of different detection methods in cleaning silicone tubes used in phacoemulsification. **Methods** A total of 100 silicone tubes were selected randomly after surgery. The silicone tubes were retained for ⩽2 hours after surgery, and then washed with a high-pressure water gun at a flow rate of 12~14 ml/s. Adenosine Triphosphate (ATP) detection and quantitation of residual protein were performed on the samples before cleaning and after washing for 30 s, 40 s, and 50 s, respectively, including the sample surface and the water after cleaning. **Results** According to the results before and after cleaning the silicone tube, there are significant differences in three methods of quantitation of residual protein, ATP detection in water sample, and ATP detection in sample surface (c^2=8.6, P<0.05), while having no difference between the three methods after washing for 30 s, 40 s and 50 s, respectively (c^2=4.918 and 5.571, P>0.05). A comparison of the means of ATP detection in water samples showed significant differences between rinses 30 s/40 s and 30 s/50 s. (Z=−7.45 and −0.08, P< 0.05); pairwise contrast of ATP detection in sample surface for rinsing 30 s/40 s, 40 s/50 s, and 30 s/ 50 s showed significant differences (Z=3.64, 14.92, and 25.86, P<0.05). The quantitation of residual protein in silicone tubes showed pass rates of 84%, 100%, and 100% for 30 s, 40 s, and 50 s, respectively. **Conclusion** Quantitation of residual protein, ATP detection in water sample, and ATP detection in sample surface are available for monitoring the cleaning quality of silicone tube. The tube should be cleaned at a 12~14 ml/s flow rate and a washing time of ⩾50 s.

KEY WORDS: silicone tube; ATP; Quantitation of residual protein; cataract

Introduction

The requirements for medical safety have become increasingly demanding in recent years, and the cleaning quality testing of medical devices has become more stringent. Therefore, microbiological testing has attracted growing attention in the healthcare industry[1]. Cataract is ranked as the top blinding eye disease in the world, and phacoemulsification is the most popular procedure for treating cataract, which is characterized by excellent surgical results and short surgical time[2]. However, the silicone tube essential for phacoemulsification, has a long and thin tube lumen. The diameter is about 2 mm, and the length is about 2 m, which makes it difficult to clean, and the quality of the cleaning cannot be directly recognized by the naked eye. The quality detection of cleaning is the key challenge of processing reusable silicone tubes. Cleaning is an important part of reusable instrument processing. Only cleaning can ensure effective sterilization, but there is currently an emphasis on disinfection and sterilization but an ignorance of cleaning. Poor cleaning of instruments may increase the patient's surgical incision infection[3]. In cataract surgery, an incomplete cleaning of the silicone tube not only increases the risk of infection but also increases the risk of toxic anterior segment syndrome (TASS)[4]. Therefore, it is espe-

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cially critical to detect the cleaning quality of silicone tubes. In this study, three methods, quantitation of residual protein, Adenosine Triphosphate (ATP) detection in water sample, and ATP detection in sample surface, were used to test the cleaning quality of silicone tubes. Based on the results obtained, the cleaning time and the amount of water used to clean the silicone tube were determined. It is reported as follows.

1 Material and methods

1.1 Materials and samples

A total of 100 sets of silicone tubes that had not been cleaned within 2 hours after phacoemulsification in Zhongshan Ophthalmic Center, Sun Yat-sen University were obtained. The silicone tubes were used by one surgeon.

1.2 Methods

In accordance with the manufacturer's recommended method, 100 sets of Phaco silicone tubes were selected and rinsed from one end of the silicone tubes using a high-pressure water gun with a water flow rate of 12~14 ml/s. In this study, the continuous rinsing time was set at 30 s, 40 s, and 50 s respectively, and the test samples were collected before washing and after washing for 30 s, 40 s, and 50 s, respectively.

ATP detection in sample surface[5] was performed by using a 3M Clean-Trace TM collecting rod to sweep the inner wall of the suction tube and the surface of the joints at both ends of the suction tube within 2 cm and then recording the values in a handheld 3M Clean-Trace ATP detector.

ATP detection in water sample[6,7] was performed by rinsing the silicone tube with a high-pressure water gun for 30 s, 40 s, and 50 s. Then the tube lumen was repeatedly rinsed five times with 5 ml of sterile water for injection drawn from a 5 ml syringe, respectively, and the rinsed sample solution was collected for testing.

Quantitation of residual protein was performed by inserting a 3M Clean-Trace Protein Cleaning Test Stick into a spare sample solution, shaking it, and then placing it into a 3M PROTECT-M Protein Residual Incubator with the temperature set to 55℃, and incubating it for 15 minutes. The results were read according to the color change compared to the standard color card.

1.3 Evaluation criteria for cleaning effect

According to the manufacturer's recommended threshold, ATP detection reaching ⩽150 RLU is recognized as qualified, and reaching >151 RLU is unqualified. The color card of residual protein culture solution standard shows green as qualified; and grey, light purple, or dark purple as light, medium, or heavy contamination respectively, which is recognized as unqualified.

1.4 Statistical analysis

SPSS19.0 was used for statistical analysis of data. Measurement data were described as mean ± standard deviation, and means were compared using the t-test with a test level of $P<0.05$. Count data were described as rate or percentage, and comparisons were made using the chi-square test with a test level of $P<0.05$.

2 Results

2.1 The contamination level of uncleaned silicone tubes was detected by quantitation of residual protein, ATP detection in water sample, and ATP detection in sample surface. The differences in the pass rate of silicone tube cleaning were statistically significant (**Table 1**).

2.2 The quantitation of residual protein, ATP detection in water sample, and ATP detection in sample surface were used to evaluate the cleaning effect of silicone tubes washed for 30 s, 40 s, and 50 s, respectively. It was found that the pass rates of the three detection methods were consistent and not significantly different from each other (**Table 1**).

2.3 Effect of three detection methods in the cleaning of silicone tube quality

There was a significant difference between the ATP detection in water samples of silicone tubes cleaned for 30 s and those cleaned for 40 s and 50 s. There was a significant difference between the ATP detection in water samples of silicone tubes cleaned for 30 s and those cleaned for 40 s and 50 s (**Table 2**).

Table 1 Results of cleaning quality of silicone tubes at different washing time (cases/%)

Item	Pass quantity of ATP detection in sample surface (%)	Pass quantity of ATP detection in water sample (%)	Pass quantity of quantitation of residual protein (%)	c^2	*P*
Before cleaning	6 (24)	2 (8)	11 (44)	8. 6	**0. 013***
Cleaning for 30 s	17 (68)	23 (92)	21 (84)	4. 918	0. 085
Cleaning for 40 s	21 (84)	24 (96)	25 (100)	5. 571	0. 06
Cleaning for 50 s	25 (100)	25 (100)	25 (100)	—	—

Note: * *P*<0. 05 is statistically significant.

The results of ATP detection in water sample, ATP detection in sample surface, and quantitation of residual protein were acceptable when the washing time of silicone tubes was 40s (**Table 3**).

3 Discussion

In phacoemulsification, the silicone tube is an important conduit for the perfused fluid to enter the patient's eye and the lens cortex to be aspirated. The cleaning quality of silicone tubes, as reusable medical devices, is directly related to patient safety. Silicone tube lumen is long and thin, easily adheres to stains, and is difficult to clean. Therefore, the cleaning quality is difficult to evaluate with the unaided eye. In this study, the cleaning quality of silicone tubes was evaluated by three different methods. It was found that all three methods were applicable to evaluate the cleaning quality of silicone tubes, among which ATP detection in water sample of tube lumen was the most reliable evaluation index.

3.1 Comparative analysis of three cleaning quality evaluation methods

The comparison of quantitation of residual protein, ATP detection in water sample, and ATP detection in sample surface shows a significant difference. After the pipe is contaminated, the failure rate of quantitation of residual protein is lower than that of ATP detection, which may be related to the interpretation of the results. The quantitation of residual protein is a subjective judgment, while ATP detection is an objective value. Therefore, the results of ATP detection are more scientific and reliable[8].

There were significant differences between the ATP detection in water sample and ATP detection in sample surface results for silicone tubes before rinsing, washing for 30 s, and washing for 40 s. The levels of ATP detection in sample surface before rinsing were generally lower than those in tube lumen, which may be related to the location of sampling. The sampling rod for ATP detection in sample surface cannot go deeper into the tube lumen and the sampling area is limited, while ATP detection in water sample sampling can collect the whole tube lumen. Therefore, ATP detection in water sample is more indicative of the contamination level inside the tube lumen before rinsing. The values of ATP detection in water sample were generally lower than the values of ATP detection in sample surface after 30 and 40 s of washing, which may be related to the sampling method as well as the nature of the contaminants. In ATP detection in sample surface, the sampling rod directly contacts the water pipe

Table 2 Comparison of mean values of silicone tubes using ATP detection in water sample and sample surface (in RLU)

Item		Mean	Group	*Z*	*P*
ATP detection in water sample	Before washing	24860			
	30 s	42. 92	30 s/40 s	−7. 45	**0. 007***
	40 s	22. 8	40 s/50 s	8. 92	0. 063
	50 s	5. 92	30 s/50 s	−0. 08	**0. 0034***
ATP detection in sample surface	After washing	31330			
	30 s	304. 92	30 s/40 s	3. 64	**0. 001***
	40 s	72. 56	40 s/50 s	14. 92	**0. 003***
	50 s	36. 32	30 s/50 s	25. 86	**0. 001***

Note: * *P*<0. 05 is statistically significant.

Table 3 Residual protein test results for silicone tubes (cases/%)

Item	Passed quantity (%)	Unpassed quantity (%)
Before washing	11 (44)	12 (56)
Washing for 30 s	21 (84)	4 (16)
Washing for 40 s	25 (100)	0 (0)
Washing for 50 s	25 (100)	0 (0)

joint and the inner wall of the tube lumen. Due to the special structure of the tube lumen, organic matter is easily deposited in the inner wall of the tube lumen, making it difficult to thoroughly clean and easy to form biofilm[9,10]. This resulted in higher values than the ATP detection in water sample. It suggests that a cleaning tool should be used to wash the inner wall of the tube lumen as much as possible to ensure the quality of the cleaning.

3.2 Time and water requirements for cleaning silicone tubes

This study investigates not only the way to detect the cleaning quality of silicone tubes but also the time requirement for cleaning. To achieve effective cleaning, a water gun with a flow rate of 12~14 ml/s is required to rinse the silicone tube lumen in more than 50 seconds. The lumen is long and thin, with a length of 2 m and a diameter of 2 mm, making it difficult to clean and monitor the cleaning effect. A medical water gun is available in CSSD, which plays a great role in the cleaning effect of the tube lumen[11]. The medical water gun applies to clean silicone tubes, and the washing time requires 50 seconds to achieve the cleaning effect.

Limitations and perspectives

ATP detection in the sample surface is to sample with a suction tube at 3 points, which poses some limitations. Quantitation of residual protein suffers from subjective judgmental differences and therefore has some bias. According to the results of this study, ATP detection in sample surface, ATP detection in water sample, and quantitation of residual protein are applicable for cleaning quality testing of ophthalmic silicone tube. ATP detection in water sample is available for cleaning quality assessment for the entire lumen, while ATP detection in sample surface or quantitation of residual protein is available for spot-checking or localized cleanliness testing.

Project fund

Guangdong Medical Research Fund Project (No. A2022420).

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