DOI: 10.11910/j.issn.2791-2043.2024.2.06

Effects of four aluminum foil placement modes in testing cavitation effect of ultrasonic cleaning machine

Xiaoying Lai[1], Zhijuan Xu[2], Wei Zheng[3*]

(*1. Central Sterile Supply Department, Zigong First People's Hospital, Zigong, Sichuan 643000, China*; *2. Central Sterile Supply Department, Sichuan Cancer Hospital, Chengdu, Sichuan 610041, China*; *3. Central Sterile Supply Department, Sichuan Cancer Hospital, Chengdu, Sichuan 610041, China*)

ABSTRACT: Objective The present study intends to compare four aluminum foil placement modes in testing the cavitation effect of an ultrasonic cleaning machine so as to provide a reference for the operation in the central sterile supply department (CSSD). **Methods** The experiments were divided into Group A, Group B, Group C, and Group D according to the aluminum foil placement modes recommended by different national guides. Each group conducted 20 experiments before and after the failure of the simulated ultrasonic cleaning machine. The four groups' operation time, false positive rate, and fault detection ability were compared. **Results** The operation time was Group A>Group B>Group C>Group D. The false positive rate of Group C was higher than that of Group A and Group D (all $P<0.008$). The fault detection ability of Group A and Group C was higher than that of Group B and Group D (all $P<0.008$). **Conclusion** The aluminum foil placement mode of Group A, i.e., one aluminum foil placed along the diagonal perpendicular to the bottom of the sink, has the shortest operation time and most reliable results, which is worth popularizing in CSSD.

KEY WORDS: Ultrasonic cleaning; Cavitation effect; Aluminum foil corrosion method; Central sterile supply department

Introduction

The Central Sterile Supply Department (CSSD) is a critical department for the prevention of nosocomial infections and the maintenance of clinical operations, with responsibility for cleaning, disinfecting, and sterilizing all reusable medical devices[1]. The level of sterility assurance relies on the exponential reduction of bioburden on instruments[2], thus highlighting the importance of cleaning steps that can substantially reduce the bioburden on instruments[3]. The ultrasonic cleaning machine is most frequently used in the CSSD, and its "cavitation effect" realizes a favorable cleaning effect for luminal instruments and complex instruments[4]. The cavitation effect can be tested using various methods such as aluminum foil corrosion, frosted glass plate, ultrasonic energy bottle, and hydrophone[5-7], among which the aluminum foil corrosion is widely applied because of its low cost, easy operation, and visualization of results[8-10]. When the cavitation effect of an ultrasonic cleaning machine is tested by the aluminum foil corrosion method, each country has different regulations on the placement of aluminum foil in its industry guidelines. Since no literature report on the comparison of different aluminum foil placement modes is available at home and abroad, the present study compares the effects of four aluminum foil placement modes on the testing effect of the aluminum foil corrosion method, as reported below.

1 Materials and methods

1.1 General information

The test materials included one ultrasonic

* **Corresponding author:** Correspondence to Wei Zheng

cleaning machine, one roll of aluminium foil, and seven steel wires. The ultrasonic cleaning machine model is AK-050SD, with ultrasonic power of 300 W and a frequency of 40 KHz; five transducers were located at the bottom of the sink. The sink is 30 cm× 24 cm×20 cm with curved corners and a maximum capacity of 14 L. It comes with its own cleaning basket. The bottom of the cleaning basket is 3 cm from the bottom of the sink, 14 cm from the water level line, and the water level line is 3 cm from the top of the sink. Biosharp's aluminium foil paper with a thickness of 15 μm and a length and width of 2 000 cm × 30 cm was used. The steel wire had a diameter of 0.2 cm and a length of 40 cm. The test temperature was 18~20℃ and the relative humidity was 40%~50%.

1.2 Methods

1.2.1 Grouping

The experiments were divided into Group A, Group B, Group C, and Group D according to the aluminum foil placement modes recommended by different national guides. Group A adopted the method required in guides from China, Group B from Japan, Group C from Germany, and Group D from British. Group A had one aluminum foil placed along the diagonal perpendicular to the bottom of the sink[11], Group B placed three sheets of aluminium foil parallel to the short side of the sink, at three equal points on the long side of the sink, perpendicular to the bottom of the sink[12]. Group C placed one sheet of aluminium foil in a tilted position according to the "bottom of the long side of the cleaning basket - top of the long side of the opposite side of the sink"[13]. Group D placed nine strips of aluminum foil in a "3×3 grid on the top plane of the sink" vertically on the bottom of the sink[14]. The underwater penetration of aluminum foil was 14 cm for all three groups except Group C, as shown in Figure 1.

1.2.2 Test preparation

(1) A total of nine stoppers were prepared to reduce aluminum foil fluttering in the test. (2) A square frame measuring 28 cm × 25 cm for Group C was made using 4 steel wires. (3) Different sizes of aluminum foil were cut according to different groups, including 40 sheets of 30 cm×18 cm for Group A, 120 sheets of 19 cm×18 cm for Group B, 40 sheets of 30 cm×27 cm for Group C, and 360 strips of 30×2 cm for Group D. Each strip was rolled up 12 mm at one end and pressed flat (as a counterweight to keep the aluminium foil perpendicular to the water in order to minimize fluttering)[15]. (4) Pre-tests were conducted to determine the appropriate exposure time for aluminum foil. Since the time adjustment of the ultrasonic cleaning ma-

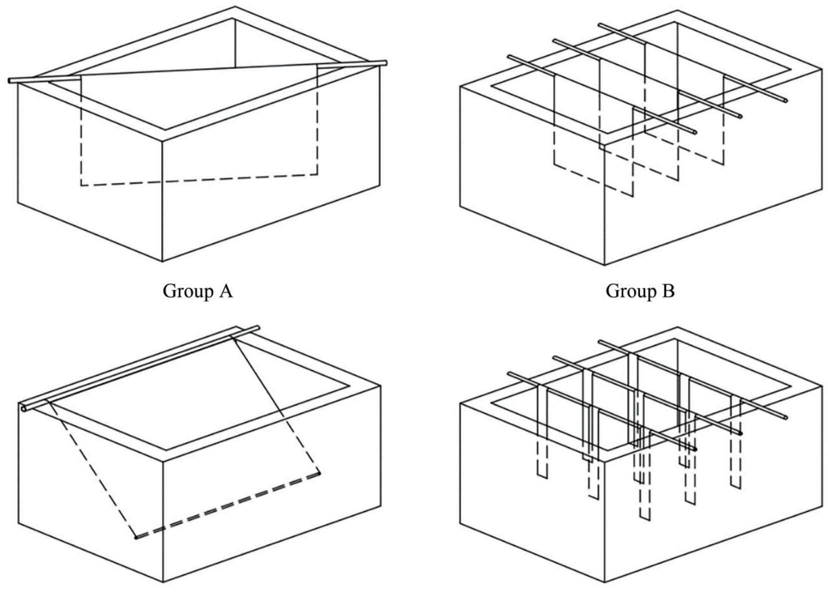

Figure 1 Schematic diagram of four aluminum foil placement modes

chine was 1 min, the exposure time was set to 1 min, 2 min, and 3 min, respectively. The exposure time of aluminum foil in this test was 2 min because the corrosion effect of aluminum foil with an exposure time of 2 min was favorable for the observation of the results.

1.2.3 Simulated pre-fault test

In each group, water was injected into the sink to the water level before the test, and heated to 40℃; the degassing program was run for 10 min; the sink was drained and cleaned after the test was completed. Group A erected the tent using one steel wire, placed one sheet of aluminium foil as specified in the test grouping; placed one stopper at each end of the aluminium foil; started the ultrasonic cleaning machine to run for two minutes; took out the aluminium foil and numbered it; dried it and stored it; all the steps after the erection were repeated for 20 times. Group B erected the stent using three steel wires, placed three sheets of aluminium foil as specified in the test grouping, and placed one stopper at each end of each sheet; the subsequent steps were same as in Group A. Group C fixed one sheet of aluminium foil on a square frame made in advance and placed it as specified in the test grouping; the subsequent steps were same as in Group A. Group D erected the stent using three steel wires and placed nine aluminum foils as specified in the test grouping, with 1 stopper for each aluminum foil; the subsequent steps were same as in Group A.

1.2.4 Simulated post-fault test

The five transducers were numbered from 1 to 5. A random number generator was used to select one transducer and cut its power supply to simulate a fault. The transducer located on the left side of the sink and the power supply close to the operation panel was cut. Following the method of operation before the simulated fault, another 20 test operations were performed for each of the four groups.

1.3 Evaluation methods

1.3.1 Operation time

The time for each operation was calculated for the different groups. It included the time for aluminum foil cutting, placement, placement of the stopper, ultrasonic exposure, removal of the stopper, removal of the aluminum foil, and numbering, and did not include the time for water injection, heating, degassing, and construction of the stent, with 40 set of data for each group.

1.3.2 False positive rate

Aluminum foil after ultrasonic exposure was considered to be a cold spot if there was no breakage within 1 square inch (2.54 cm×2.54 cm) and no impact crater from the cavitation effect[7,11]. Since the width of each aluminum foil in Group D was only 2 cm, the number of cold spots was located in a rectangular box of 3.22 cm×2 cm, and the remaining three groups were located in boxes of size 1 square inch. The number of tests in which cold spots appeared in the first 20 pre-fault tests in each group was recorded.

1.3.3 Fault detection ability

The difference between the number of cold spots before and after the fault was defined as the fault detection ability of the group. The larger the difference, the higher the fault detection ability.

1.4 Statistical analysis

Statistical analysis was performed using SPSS 23.0. Continuous variables were tested for normal distribution, and described as means ± standard deviation or as medians with the interquartile range based on the data distribution. Kruskal-Wallis H test was used for comparisons between multiple groups. Count data were expressed as frequency and percentage (%), and the comparison between groups was conducted by χ^2 test with a test level $\alpha=0.05$. Further, pairwise comparison was performed using Bonferroni Correction with $\alpha=0.008$.

2 Results

2.1 Comparison of operation time in four groups

The operation time was not identical in the four groups ($P<0.05$), as shown in Table 1. The operation time of Group A was the shortest, and the operation time of Group C, Group B, and Group D increased in order; the pairwise comparisons were statistically significant ($P<0.008$), as shown in Table 2.

Table 1 Comparison of operation time in four groups (s, $\bar{x} \pm s$)

Group	n	Operation time (s)
Group A	40	204. 18±11. 34
Group B	40	371. 33±23. 74
Group C	40	259. 70±13. 84
Group D	40	858. 20±91. 61
H	149. 08	
P	<0. 001	

Table 2 Pairwise comparison of operation time in four groups

Groups compared	*Z*	*P*
Group A-Group B	−80. 00	<0. 001
Group A-Group C	−40. 00	<0. 001
Group A-Group D	−120. 00	<0. 001
Group C-Group B	40. 00	<0. 001
Group C-Group D	−80. 00	<0. 001
Group B-Group D	−40. 00	<0. 001

2.2 Comparison of false positive rate in four groups

The false positive rate was not identical in the four groups (P<0.05), as shown in Table 3. Group C had a higher false positive rate than Group A and Group D (χ^2=7.62, P=0.006). The difference between the remaining two groups was not statistically significant.

Table 3 Comparison of false positive rate in four groups (case, %)

Group	n	cold spot	
		Yes	No
Group A	20	2 (10)	18 (90)
Group B	20	6 (30)	14 (70)
Group C	20	10 (50)	10 (50)
Group D	20	2 (10)	18 (90)
χ^2	11. 73		
P	0. 008		

2.3 Comparison of fault detection ability in four groups

The fault detection ability was not identical in the four groups (P<0.05), as shown in Table 4. The fault detection ability of Group A and Group C was greater than that of Group B and Group D, and the difference was statistically significant (P<0.008), as shown in Table 5.

Table 4 Comparison of fault detection ability in four groups [n, M (P_{25}, P_{75})]

Groups compared	n	Difference in number of cold spots
Group A	20	4 (3. 25, 5)
Group B	20	3 (2, 3)
Group C	20	4. 5 (3. 25, 5)
Group D	20	1. 5 (1, 2)
H		43. 94
P		<0. 001

Table 5 Pairwise comparison of fault detection ability in four groups

Groups compared	*Z*	*P*
Group A-Group B	21. 38	0. 003
Group A-Group C	−4. 25	0. 555
Group A-Group D	37. 58	<0. 001
Group C-Group B	−25. 63	<0. 001
Group C-Group D	41. 83	<0. 001
Group B-Group D	16. 20	0. 024

3 Discussion

The procedure for testing the cavitation effect of an ultrasonic cleaning machine using the alumina foil corrosion method includes preparing the stent, cutting and placing the alumina foil, placing the stopper, ultrasonic exposure, removing and numbering the stopper, drying the aluminum foil, and interpreting the results. The operation time was influenced by factors such as the number and position of the stent, and the number and shape of the aluminium foil. In this study, the operation time was Group A>Group B>Group C>Group D, and the differences were statistically significant. Group A with the shortest operation time required only one stent and one aluminum foil[11]. It took less time to erect one stent as diagonally placed. The ends of the steel wire were placed diagonally across the top of the sink and fixed, rather than being measured multiple times for the midpoint location as Group B and Group D did. A test using one sheet of aluminum foil took significantly less time to cut, place, remove, and number the stopper than the 3 sheets of Group B and the 9 strips of Group D. Group D took the longest time with 3 stents and 9 strips of aluminum foil[14,15]. The center point required several measurements during the stent erection because the alumina foil strips were placed on a "3×3" grid in Group D. The preparation of the aluminum foil strips took the most time, as nine strips of aluminum foil were cut for each test, and 12 mm of the bottom end of each strip was rolled up and flattened before being placed in the sink so as to receive the ultrasound exposure. Moreover, the bulge at the bottom of each strip blocked the ultrasonic transmission from the bottom to the top instead of fixing the position of the aluminum foil as expected. The operation time for both Group B and Group C increased because Group B built three stents and used three sheets of aluminum foil and Group C fixed the alumina foil around the square frame.

A cold spot found in the test results before the simulated fault was defined as a positive event. The ratio of the number of positive events to the total number of occurrences in each group is the false positive rate. Group C had a higher false positive rate of 50% than Group A and Group D, with the difference being statistically significant. The false positive rate in Group C was higher than that in Group B, but the difference was not statistically significant, which may be related to the insufficient sample size. Group C had the highest false positive rate, probably caused by the aluminium foil not being inserted vertically into the water. Similar to the common ultrasonic cleaning machines in the market[16], the transducer of the ultrasonic cleaning machine used in this study was located at the bottom of the sink. The ultrasonic waves emitted by the transducer were transmitted upward from the bottom of the sink and were fully reflected when they met the liquid surface (the absolute soft interface formed by the "liquid-air boundary"[17]). Standing waves were formed by the superposition of incident and reflected waves with the same frequency and amplitude and opposite propagation directions[16]. Wave nodes (no cavitation effect) and wave loops (strongest cavitation effect) of standing waves were in fixed and alternating positions[18], suggesting that "strong cavitation effect" and "no cavitation effect" existed vertically and alternately in the water and that each layer was the thinnest in the vertical direction. In Group C, the vertical distance between the alumina foil and the liquid surface was 14 cm from the bottom of the cleaning basket, and the length of the alumina foil into the water was 23 cm, with the bottom of the sink as 0°. The tilt angle of the aluminum foil was 37.5° according to the inverse chord function. At the same height of the liquid level, the thickness of the layers corresponding to the aluminum foil in Group C increased by 1.64 times (23/14) compared to that in the vertical direction, which enlarged the area of the cavitation effect and widened the range of missing and weak cavitation effect, thus making a higher possibility of cold spots in the aluminum foil of Group C.

The fault was simulated by cutting the power supply of one transducer during the test. At this time, the remaining transducers transmitted ultrasonic waves as normal, the wave interfered, and ultrasound was reflected[19] so that a weak cavitation effect still existed directly on top of the inoperative transducer. The groups differed in their fault detection ability because different forms of aluminum foil had different effects on the cavitation effect at the fault and recording abilities. The larger the difference in the number of cold spots before and after the simulated faults, the higher the fault detection ability. The fault detection ability of Group A and Group C is higher than that of Group B and Group D, and the difference is statistically significant. The fault detection ability is the same between Group A and Group C, and Group B and Group D. The low fault detection ability of Group B may be attributed to the fact that the three parallel-placed aluminum foils have a greater influence on the ultrasonic reflection, which enhances the localized cavitation effect at the fault. The fault detection ability of Group D is very low because the width of the aluminum foil strip in Group D is only 2 cm. The height range of the number of cold spots was 3.22 cm, which was higher than that of the other groups (2.54 cm), in order to calculate the number of cold spots per square inch. "Strong cavitation effect" and "no cavitation effect" alternated vertically in the water due to the presence of the ultrasonic standing waves (the distance between the center areas of the two layers was 0.95 cm at a water temperature of 40℃[20]). Group D had a longer interpretation height than the other groups and could contain more areas with a strong cavitation effect. As a result, the number of cold spots in the simulated post-fault test was lower. However, due to the narrow width of the aluminium foil strip, especially in the case of damage to the edges caused by the process of cutting, placing, and removing the aluminium foil strip, the number of interpreted cold spots may be lower than the actual value.

4 Conclusion

The aluminum foil corrosion method is a prevalent method used by CSSD to test the cavitation effect of ultrasonic cleaning machines. Considering the operation time, false positive rate, and fault detection ability of the four different placement modes, the method recommended by the Chinese industry guidelines is preferred because of its short operation time and reliable results. In this study, only a small ultrasonic cleaning machine was tested, and the cavitation effect of a bigger ultrasonic cleaning machine in CSSD using the aluminum foil corrosion method is yet to be explored. The aluminum foil corrosion method, frosted glass plate method, and ultrasonic energy bottle method for testing the cavitation effect tend to be qualitative or semi-quantitative, and the difficulty of testing is dependent positively on the size of the cleaning machine. Therefore, quantitative, automated, and multidimensional testing methods will be the future attractions.

References

[1] H.J. Si, L. Jia, Y.L. Wang, et al, "Research on the value of 5G technology combined with the Internet of Things intelligent quality traceability system in continuous quality improvement of central sterile supply department," *China Medical Equipment*, vol. 20, pp. 118-122, 2023.

[2] General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China, Standardization Administration of the People's Republic of China. Part 1: Determination of a population of microorganisms on products: GB/T 19973.1—2015 [S]. Beijing: 2015.

[3] Y.M. Duanmu, X. Liu, Y. Yang, et al, "Effect of 3 % hydrogen peroxide as a preprocessing method on cleansing quality of surgical metal suction cannula," *Journal of Nursing Science*, vol. 35, p. 44, 53, 2020.

[4] P. Zhang, D.Z. Liang, X.B. Zhao, et al, "Observation and analysis of the cleaning efficacy of de-biofilm cleaning agent coordinated with vacuum ultrasonic cleaning machine on lumen apparatus," *China Medical Equipment*, vol. 18, pp. 44-47, 2021.

[5] W. X. Tan, K. W. Tan and K. L. Tan, "Developing high intensity ultrasonic cleaning (HIUC) for post-processing additively manufactured metal components," *Ultrasonics*, vol. 126, p. 106829, 2022.

[6] B. Verhaagen and D. Fernández Rivas, "Measuring cavitation and its cleaning effect," *Ultrasonics Sonochemistry*, vol. 29, pp. 619-628, 2016.

[7] Liu L, Gan J L, Zhang S H, et al. Methods for monitoring the cleaning effect of ultrasonic cleaning machine and the factors affecting it [J]. Chinese Journal of Disinfection, 2016, 33(06): 603-604.

[8] J. Choi and Y. Son, "Quantification of sonochemical and sonophysical effects in a 20 kHz probe-type sonoreactor: Enhancing sonophysical effects in heterogeneous systems with milli-sized particles," *Ultrasonics Sonochemistry*, vol. 82, p. 105888, 2022.

[9] P. Cao, C. Hao, C. Ma et al., "Physical field simulation of the ultrasonic radiation method: an investigation of the vessel, probe position and power," *Ultrasonics Sonochemistry*, vol. 76, p. 105626, 2021.

[10] L.P. Tu, "Ultrasonic cleaning of locomotive electrical circuit," Nanchang: East China Jiaotong University, 2020.

[11] H. Huang, X.L. Zhou and H. Chen, *Guide to the management of hospital disinfection supply center.* Beijing: Research Press, 2019: 223-226.

[12] 一般社団法人日本医療機器学会 . 医療現場における滅菌保証のガイドライン [S]. 東京都: 2021.

[13] Deutsche Gesellschaft für Supervision und Coaching e. V. Guideline for validation of manual cleaning and manual chemical disinfection of medical devices [S]. Köln: 2013.

[14] National Health Service in England. Decontamination: Health Technical Memorandum 01-05: Decontamination in primary care dental practices [S]. London: 2013.

[15] National Health Service Estates. HEALTH TECHNICAL MEMORANDUM 2030 Washer disinfectors: Validation and verification [S]. London: 1997.

[16] Z.H. Wang, *Ultrasound cleaning technology.* Wuhan: Wuhan University of Technology Press, 2019: 41-53.

[17] L. K. Ma, Y. C. Ji, G. Q. Shen, et al, “Experimental study on the influencing factors of ultrasonic cavitation,” *Journal of Applied Acoustics*, vol. 38, pp. 999-1003, 2019.

[18] M.L. Shan, Y.L. Yang, Y.P. Zhu et al., “Optimization of clean sound field uniformity by sound source distribution and ultrasonic frequency pairs,” *Journal of Applied Acoustics*, vol. 37, pp. 475-480, 2018.

[19] Y. W. Shi. *Ultrasound Detection*. Beijing: China Machine Press, 2005: 14.