Original Article

ATP-based measurements for evaluating the washing of surgical instruments prior to use: a multi-center study

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The test kit for this study was provided by Kikkoman Biochemifa Company and 3M Company.
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Abstract

The cleaning result in an automated washer disinfector (WD) can be assessed by measuring the cleanliness of the surgical instruments after washing, but visual inspection does not give a quantitative result. Moreover, the method for measuring residual protein on surgical instruments is unsuitable for onsite evaluation because it is not rapid.

Adenosine triphosphate (ATP) provides energy for cellular metabolism and is present in all living cells. Accordingly, it is an excellent marker for evaluating contamination by organisms.

In this study, we aimed to measure the ATP on soiled surgical instruments, washed at 11 medical facilities in Japan and sought to identify values that could serve as reference criteria for washing evaluation.

The results suggest that ATP measurement can be considered a valuable tool for the appropriate evaluation of WD washing in real time. ATP reference values of 100 RLU for PL and 150 RLU for NU could serve as evaluation criteria for surgical instruments.

Keywords
- surgical instruments
- cleaning
- cleaning evaluation
- ATP

Background

The effectiveness of an automated washer disinfector (WD) in cleaning soiled surgical instruments can be assessed by measuring the cleanliness of the surgical instruments after washing but this cannot be performed quantitatively through direct vision. Moreover, the method for measuring residual protein on surgical instruments after washing with WD is unsuitable for onsite evaluation because it is not rapid [1, 2].

Adenosine triphosphate (ATP) provides energy for cellular metabolism and is present in all living cells. Accordingly, it is an excellent marker for evaluating contamination by organisms. Moreover, by employing ATP measurement for the objective and quantitative evaluation of washing efficiency, results can be obtained in near real-time since the measurement is completed within about 30 seconds. Visrodia et al. reported that based on these characteristics, ATP measurement is effective as a reprocessing assessment tool for medical equipment [3].

Surgical instruments that are used invasively must be aseptic to prevent surgical site infections (SSIs). Appropriate surgical instrument sterilization leads to reduced SSI rates and the evaluation of sterility before instrument use presumably contributes to SSI prevention [4].

Alfa et al and Parohl et al proposed, as a washing evaluation criterion after using the gastrointestinal flexible endoscope, that if the ATP measurement

Table 1: Facility C had extra drying after preliminary washing. Facility H washed at different temperatures in the main washing. Facility I used at different detergent and concentration in the washer disinfector, and washed at different temperatures in the main washing, and dried at different in the drying. Facility J used at different detergent in the washer disinfector. Facility K washed it with two different machines, concentration, preliminary washing time, and rinse time in the washer disinfector.
NE: The concerned articles is not executed.

Table 1: Cleaning protocols used at all the 11 participating institutes

	Preliminary washing						Washer disinfector																
	Detergent				Washing		Machine			Detergent			Preliminary washing			Main washing		Ultra-sound washing		Rin-se	Hot water disinfec-tion		Drying	
Facility	Product name	Manufacturer	Producing country	Concentration (%)	Temperature (°C)	Time (min)	Product name	Manufacturer	Producing country	Product name	Manufacturer	Producing country	Concentration (%)	Time (min)	Number of times	Temperature (°C)	Time (min)	Temperature (°C)	Time (min)	Time (min)	Number of times	Temperature (°C)	Time (min)	Temperature (°C)
A	HKP-101M	HKP	Japan	1	45	20	86 series	GETINGE	Sweden	HKP-101M	HKP	Japan	0.5	0.5	2	40	8	NE	NE	1	3	90	5	90
B	Power Quick Multi-enzy-me Cleaner	SARAYA	Japan	1	40	10	88 turbo	GETINGE	Sweden	GETINGE CLEAN Alkaline Cleaner	GETINGE	Sweden	0.5	2	1	60	12	NE	NE	2	2	90	5	90
C	NeoARbest WE	ARBOS	Japan	0.5	40	5	46 series	GETINGE	Sweden	GETINGE CLEAN Alkaline Cleaner	GETINGE	Sweden	0.4	1	1	55	10	NE	NE	1	2	90	5	90
D	Power Zyme	AMTEC	Japan	0.4	40	10	MU-810	SHARP	Japan	M580L	SHARP	Japan	0.5	3	1	40	5	40	5	1	2	90	5	120
E	Biotect 55	SAKURA SEIKI	Japan	0.3	40	10	WUS-210	SAKURA SEIKI	Japan	Biotect DX	SAKURA SEIKI	Japan	0.3	3	1	50	5	50	10	1	2	93	10	110
F	Dr.2000	Canon Lifecare solutions	Japan	0.74	40	15-30	88 turbo	GETINGE	Sweden	GETINGE EXTRA	GETINGE	Sweden	0.5	2	1-2	60	5	NE	NE	1	1-2	90	10	90
G	NE	NE		NE	NE	NE	WUS-3400	SAKURA SEIKI	Japan	Biotect DX	SAKURA SEIKI	Japan	0.3	2	1	45	8	45	5	1	3	93	10	120
H	Must Zyme	NICCA CHEMICAL	Japan	0.4	40	20	WUS-3100	SAKURA SEIKI	Japan	Alka Challenge	GINOVA medical	Germa-ny	0.7	3	1	55 90	5	45	5	1	3	93	1	110
I	NE	NE		NE	NE	NE	DS-1000 2S	STEELCO	Italia	MS-AW MS-EW	MS	Japan	0.5 0.7	3	1	90 50	5 15	NE	NE	1	2	90	1 5	80
J	NE	NE		NE	NE	NE	HAMO T-21 NGC	STERIS	Ohio	Prolystica-Alkaline Prolystica-Neutrality enzyme	STERIS	Ohio	0.047	1	2	50	8	NE	NE	1	1	91	2.5	110
K	NE	NE		NE	NE	NE	86 series 88 turbo	GETINGE	Sweden	GETINGE CLEAN Alkaline Cleaner	GETINGE	Sweden	0.37 0.35	5 1	2	80	10	NE	NE	2 1	2	90	5	110

on the endoscope surface after hand cleaning shows a value of 200 relative light units (RLU) or above, reprocessing should be performed [5–7]. However, no study has suggested or investigated washing evaluation reference values based on ATP measurement, as a measure of improper washing. Moreover, in ISO 15883-1, although ATP measurement was listed as a washing evaluation method for the washer disinfector (WD) in the washing of stainless steel surgical instrument etc., no clear washing efficiency evaluation criteria were specified [8].

In this study, we aimed to measure the ATP on soiled surgical instruments, washed at 11 medical facilities in Japan and sought to identify values that could serve as reference criteria for washing evaluation.

Materials and Methods

Surgical instrument washing protocol

Table 1 shows the washing protocols and conditions of the surgical instruments used in the 11 medical facilities. Seven facilities performed pre-washing by immersing in an enzyme detergent solution before washing with WD. The seven facilities used different detergents and protocols. With respect to the WD model, hospitals A to K used 86 series (GETINGE, Sweden); and B, E, and K used the 88 turbo (GETINGE) model. Regarding the detergent used in washing with the WD, facilities B, C, and K used GETINGE CLEAN Alkaline Cleaner (GETINGE), whereas facilities E and G used Biotect DX (SAKURA SEIKI, Japan). Although some facilities used the same protocol in specific processes of WD pre-washing, main washing, WD ultrasound washing, rinsing, hot water disinfection, and drying, no two facilities used the same protocol consistently across all the processes.

ATP measurement instrument and the test kit and test surgical instruments

The ATP measuring instruments used were Lumitester® PD-30 (PD-30) and CleanTrace™ NGi (NGi), and the corresponding exclusive detergents used were LuciPac® Pen (Pen) and CleanTrace™ UXL (UXL), respectively. The soiled surgical instruments in the 11 medical institutions were tested in 2016. The minimum and maximum number of surgical instruments assessed for ATP with PD-30 and Pen (PL) in facilities A to K were 46 and 57, respectively, and the minimum and maximum number of instruments assessed for ATP with NGi and (NU) were 42 and 58, respectively. Moreover, among the various types of surgical instruments tested, forceps exhibited the highest value for both PL and NU (Table 2).

Table 2: Details of various instruments tested at each of the 11 institute with both the testing devices

	Lumitester® PD-30 & LuciPac® Pen						CleanTraceTM NGi & Clean TraceTM UXL					
Facility	Total number	Scissors	Forceps	Needle holders	Others	Subtotal	Total number	Scissors	Forceps	Needle holders	Others	Subtotal
A	57	32	15	5	5	114	58	33	11	7	7	116
B	54	25	13	10	6	108	50	24	12	7	7	100
C	51	34	7	10	0	102	50	31	10	9	0	100
D	55	39	8	8	0	110	50	24	14	12	0	100
E	53	21	12	4	16	106	50	16	8	7	19	100
F	55	40	9	5	1	110	53	38	9	5	1	106
G	53	27	15	10	1	106	55	35	10	9	1	110
H	57	26	13	13	5	114	52	26	14	7	5	104
I	46	28	10	8	0	92	42	22	7	13	0	84
J	53	33	7	10	3	106	54	33	7	5	9	108
K	54	41	7	5	1	108	58	40	12	5	1	116

Baseline measurement

Regarding the ATP measuring instruments, a measurement value of 0 RLU may not be obtained in some cases because even if ATP does not exist, a trace amount of ATP may be contained in the cotton swab used for wiping or in the luminescent detergent. Accordingly, the baseline was measured for each measurement method to verify its influence on the measured values. Five measurements each were conducted for PL after immersing the cotton swab portion in purified water and for NU immediately after opening the detergent and pressing down the cotton swab on the detergent used in measurement. Thereafter, the mean for each detergent was calculated.

ATP measurement of the test surgical instruments

Using PL or NU, ATP was measured for the test surgical instruments after the completion of all steps from preliminary washing using WD to drying. Regarding the measurement environment, the room temperature range was 21.9 to 26.3 ° C and the ATP measurement test kit was left at room temperature for one hour or more before use. For sample collection, a surface other than the finger holes of the surgical instrument was wiped (back and forth) three times using the respective exclusive cotton swabs. With a target load of 75 g from the swab on the surgical instrument, the same person performed all the measurements, and only one measurement (3 round trips with cotton swab) was performed for each surgical instrument. The lot numbers of the test kit used in the ATP measurement were 20161025 U and 20160429 T for Pen and 1516 C and 1463 C for U.

Statistical analysis

Statistical analysis was performed with JMP 7.0 (Analytics Software & Solutions Institute incorporated, North Carolina, USA).

Results

Figure 1 shows the baseline measurements for confirming the accuracy of ATP measurement at facilities A to K. The ranges for PL and NU were 2.9–6.1 RLU and 11.0–34.7 RLU, respectively. For facilities A to K, the median measurement values were 11.0, 12.5, 15.0, 10.0, 13.0, 29.0, 9.0, 12.0, 26.0, 35.0, and 54.5 RLU, respectively, for PL (Figure 1b) and 20.5, 18.0, 17.0, 53.5, 21.0, 34.0, 23.0, 22.5, 38.5, 57.0, and 52.5 RLU, respectively, for NU (Figure 1c). The median, standard error, and one-sided upper 95% confidence interval were 15.0, 12.3, 97.2 RLU, respectively, for PL and 25.0, 21.2, 145.1 RLU, respectively, for NU (Table 3).

Discussion

The results suggest that 100 RLU for PL and 150 RLU for NU may be considered the reasonable ATP evaluation reference values that could serve as WD washing evaluation criteria. In statistics, the 95% confidence interval indicates that the population average is within that range with a 95% probability. Applying this concept to the results of the study, it is estimated that for all ATP measurements of surgical instruments at the 11 medical facilities, PL values lower than 97.2 RLU and NU values lower than 145.1 RLU have a 95% probability of being obtained.

Although a method based on 2 standard deviation has been proposed for the ATP measurement value as a measure of reprocessing the flexible endoscope, there are many issues such as determination of the appropriate number of samples necessary, time and labor for sampling, difficulty of data analysis, and incomparability with other facilities [6]. Moreover, although an indirect washing evaluation indicator is commercially available, in which pseudo-contaminants such as hemoglobin and various dyes are adhered to a stainless-steel plate or a plastic sheet, there are issues such as a suitable place of installation within the WD, the relationship between pseudo-con-

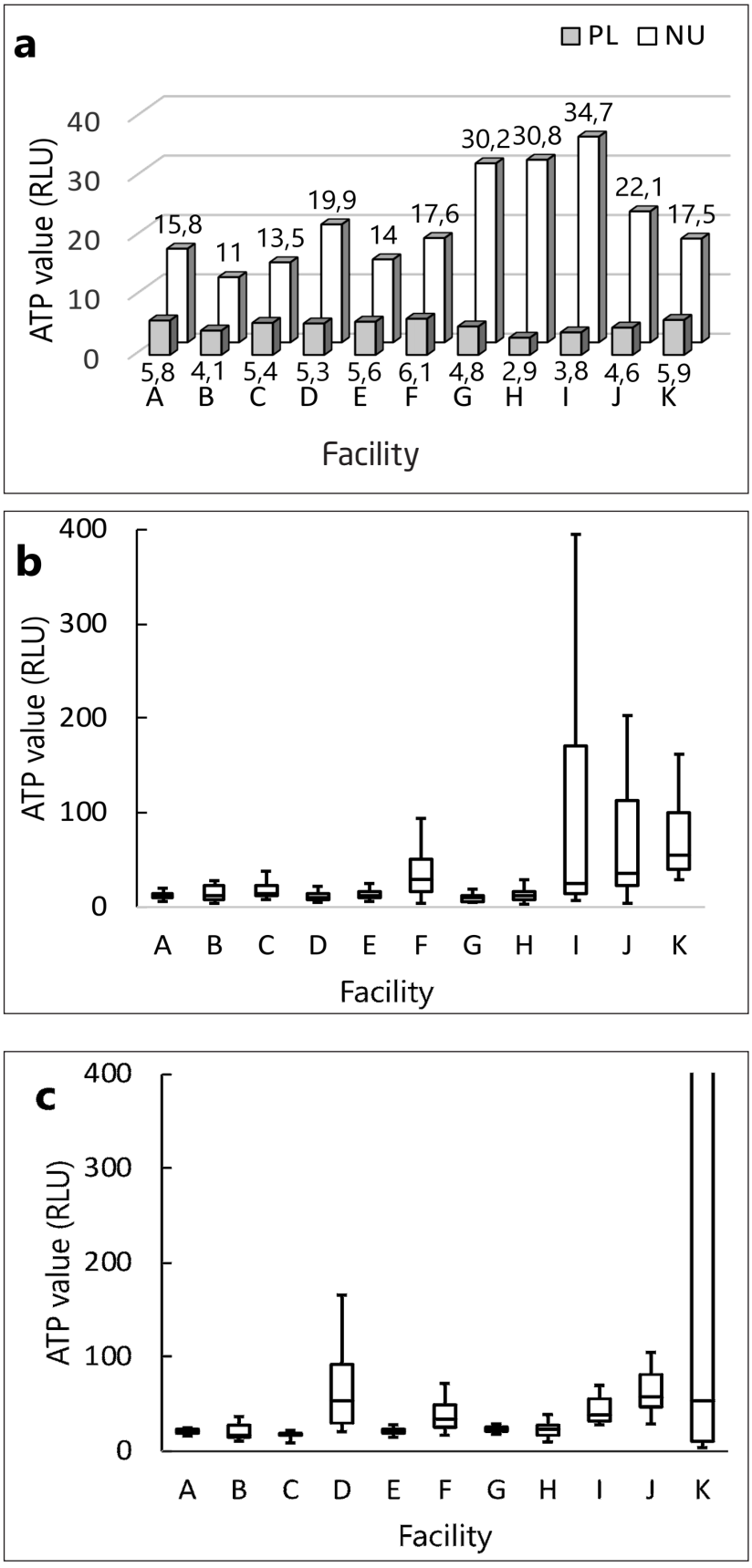

Fig. 1: Baseline measurements for confirming the accuracy of ATP measurement at facilities A to K. **1 a**: Results of Baseline measurements. PL: Lumitester® PD-30 and LuciPac® Pen, NU: CleanTrace™ NGi and Clean Trace™ UXL. **1 b**: Results of median ATP measurement values on surgical instruments at facilities A to K as assessed using PL. **1 c**: Results of median ATP measurement values on surgical instruments at facilities A to K as assessed using NU.

taminants and actual pollutants, and the fact that the method essentially is an indirect evaluation. In Germany, although the washing evaluation criteria for WD based on the amount of residual protein on surgical instruments [7] have been adopted, there are inherent problems such as complicated procedures for extraction and measurement, the necessity of a spectrophotometer to measure the absorbance of the coloring solution, and the infeasibility of real-time evaluation.

This study is based on more realistic results because the ATP value was measured immediately after the soiled surgical instruments were washed with WD at the 11 participating medical facilities. Moreover, the use of the 95% confidence interval as a reference value has been applied for evaluating blood glucose level and red blood cell count in clinical examination. By adopting the same approach, the present study proposes more versatile washing evaluation criteria.

However, since the evaluation criteria in this study are based on data collected at only 11 medical facilities in Japan, it is unclear whether they are applicable as the washing evaluation criteria for all medical facilities, where equipment such as WD are used for washing surgical instruments. Among all the medical facilities that participated in this study, no two facilities adopted identical washing protocols. This is because the WD washing protocol had been customized for each facility. However, the fact that a certain washing effect had been noted, even with customized cleaning protocols, suggests that the results of the present study may be applicable as washing evaluation criteria in many other medical facilities.

The study has three limitations. The first one is the inability to specify which approach is better, whether to measure the ATP on all surgical instruments washed with WD or to randomly select the instruments after WD washing and measure for ATP. Although the latter approach is more realistic since measuring ATP on all surgical instruments is not practical, the random selection of test surgical instruments necessitates that the generated bias be verified. The second one is regarding the inability to evaluate reproducibility near the measured values, especially for the values that serve as the washing evaluation criteria, since the baseline results suggest that the accuracy (reproducibility) of NU is lower than that of PL. Depending on the accuracy of NU, re-examination may be necessary regarding the NU criterion value. With respect to the third limitation, the degree of contamination of the surgical instruments before washing could not be evaluated in this study. It is also necessary to study the influence of the degree of contamination (before washing) on the measurement results and if the ATP value is proportional to the swabbed total surface area, which could then vary depending on the size of the surgical instrument.

Conclusion

The results of the study suggest that ATP reference values of 100 RLU for PL and 150 RLU for NU could serve as WD washing evaluation criteria for surgical instruments. The results of the study suggest that if the values proposed here are used in WD daily, they will most likely secure a constant washing effect. Accordingly, ATP measurement can be considered a valuable tool for the appropriate evaluation of WD washing in real time.

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References please see p. 153

Table 3: Median RLU values for all the instruments analyzed using the 2 commercial kits (PL and NU)

Methods	Number	Median	Standard error	One-sided upper 95% confidence interval
PL	588	15	12.3	97.2
NU	572	25	21.2	145.1

(PL) Lumitester ® PD-30 & LuciPac ® Pen, (NU) CleanTrace™ NGi & Clean Trace™ UXL
Median, Standard error and One-sided upper 95% confidence interval are expressed in Relative Light Units