The Utility of an ATP System for Monitoring the Cleanliness of Surgical Instruments.

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Introduction

Reprocessing surgical instruments requires verification of cleanliness during wash and disinfection. Currently, the primary means of verifying cleanliness relies on visual inspection. However, visual assessment has obvious and significant limitations. In rare cases, reprocessing procedures are monitored by microbial cultures or more likely, by determination of residual blood or protein on the actual instruments. There are also standards that call for the need to carry out mandatory testing of washer disinfectors (HTM2030, paragraphs 10.37 to 10.51; ISO 15883-1 First Edition 2006-04-15, Part 1, Annex C). The standards recommend that items processed in the washer disinfectors of a hospital Sterile Service department be tested for 'residual soil' after cleaning, at least once a week. Standard testing has traditionally used protein detection procedures based on ninhydrin reagents[1,2], but this technique is laborious, requiring the use of incubators, and the preparation of assay reagents. In addition there are other significant disadvantages:

- Results are not immediately available.
- The presence of bacteria may easily be missed because some organisms require specific growth conditions and long culture time.
- Interpretation of the results of residual protein tests is highly subjective because it usually requires comparison to a color chart.

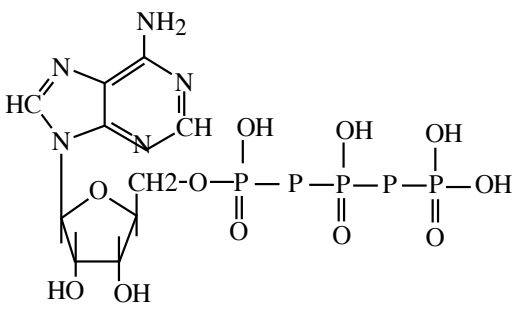
Methods to verify the cleanliness of surgical instruments during wash and disinfection should be easy to use and provide results in real time in order to allow timely intervention. Amongst potential methods that could be used in the manner described above, assays based on the detection of adenosine triphosphate (ATP) as a marker for organic biomatter, may be extremely appealing. ATP is an indicator of organic as well as microbial contamination because it is a constituent of all living cells and is present in bacteria and cells of animal or plant origin. As a result, ATP assays are commonly used to assess environmental cleanliness, primarily in food processing applications, and to determine contamination levels in water samples[3,4]. More recently, ATP assays have been used with success in clinical settings to rapidly assess cleanliness and the adequacy of the cleaning procedures for patient rooms[5-7], and in a few cases, to assess the cleanliness of surgical instruments prior to terminal sterilization[8,9]. In this paper we describe the results of a study where the 3M™ Clean-Trace™ ATP system was used to assess and measure the level of cleanliness of surgical instruments at various points in the decontamination and cleaning process, prior to high level disinfection and terminal sterilization. The 3M™ Clean-Trace™ ATP system was not used as an indicator of high level disinfection or sterilization.

Methods

The 3M™ Clean-Trace™ ATP Surface Test uses an ATP bioluminescence technology enabling the user to assess the cleanliness of a surface and determine the efficacy of cleaning protocols in less than one minute. ATP technology is based on the fact that ATP, the universal energy storage molecule (Structure I), is present in all living cells. This makes ATP an ideal marker for environmental surface cleanliness as all biological residues (microbes, food, plants, human cells and fluids) contribute to the ATP signal. However, it is also important to note that ATP based systems cannot detect contamination in situations where the soil may be composed solely of proteins, and there are no active metabolizing cells. For example, detecting the etiologic agents of Transmissible Spongiform Encephalopathies (TSE) and Toxic Anterior Segment Syndrome (TASS) would not be possible.

ATP is measured indirectly using a luciferin-luciferase bioluminescence assay. The enzyme luciferase uses ATP and the protein luciferin to generate a light signal which is quantified using the hand-held 3M™ Clean-Trace™ Luminometer. The light signal is measured in Relative Light Units (RLUs). The relationship between the amount of ATP and the amount of light produced is linear on a log scale. The more organic residue that is present on a surface, the more ATP is present, the more light is produced. The Clean-Trace ATP Surface Test provides a rapid, objective measurement that quantifies surface cleanliness. Using predetermined Pass/Fail values, objects and surfaces at risk for cross-contamination can be tested to ensure proper cleaning has taken place.

Structure I



adenosine triphosphate (ATP)

The data discussed in this paper were collected from three distinct clinical sites. The protocol used was as follows:

1. With assistance from sterile processing department (SPD) personnel, we chose 3–5 instruments per instrument set to be assessed such that:
   a. At least 1 instrument is considered dirty/heavily soiled and hard to clean
   b. At least 1 instrument is considered dirty/heavily soiled and relatively easy to clean
   c. At least 1 instrument is considered lightly soiled

2. We sampled and tracked instruments through each step in the decontamination process: prior to cleaning (e.g. receiving and inspection of instrument sets), after manual washing, and finally, after processing through a washer-disinfector.

3. At each step in the instrument decontamination process, we sampled the chosen instrumentation at the same test points as follows:
   a. At each step in the decontamination process and before sampling test instruments, we ran a 3M™ Clean-Trace™ swab blank (no sample) to establish the background reading.
   b. The test points included:
      i. one swab to sample the entire surface
      ii. one swab to sample heavily soiled area
      iii. one swab to sample cannulae, lumens, openings, crevices, between blades, between mated surfaces, etc.
      iv. one swab to sample surface that is visually clean or lightly soiled
   c. In each case, we noted the type of instrument and area where swab samples were obtained so that the same areas could be sampled as the instruments progressed through decontamination
   d. Swabbing was performed by:
      i. Removing the swab from its protective cover
      ii. Applying enough pressure to cause the swab shaft to bend slightly, moving the swab in a zigzag fashion over sample area
      iii. Returning the swab to the protective cover
      iv. Pushing on the end of the swab hard enough for the swab to break the protective barrier at the bottom of the swab cover
      v. Mixing the swab/cover by shaking rapidly from side to side for approximately 5 seconds, then immediately placing in the luminometer to obtain an RLU reading

Table I shows the instruments tested as well as the test point swabbed on a given instrument at each of the clinical sites. The instruments tested were either part of an orthopedic tray or a general surgery tray.

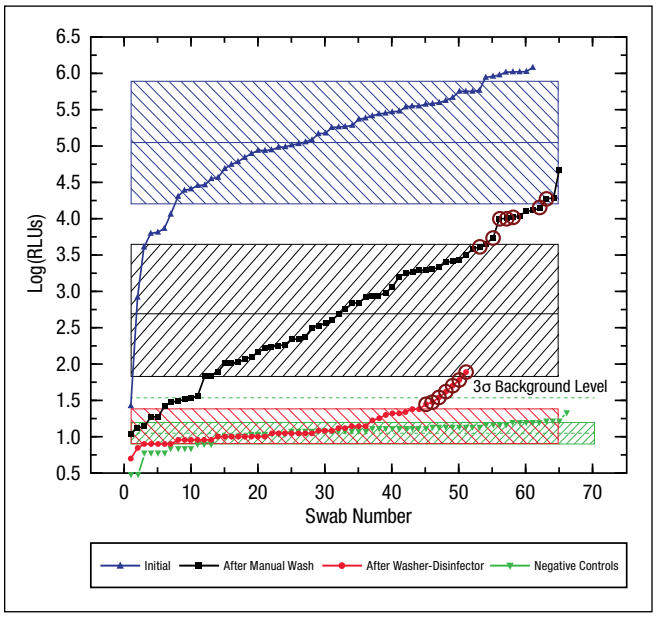
Table I – Summary of the surgical instruments tested

Clinical Site	Instrument Type	Instrument Number	Swabbed Test Point
1	Trial-ball	1	Total surface
1	Trial-ball	1	Outside surface
1	Trial-ball	1	Inside surface
1	Hip Impactor	2	Total surface
1	Hip Impactor	2	Plastic tip
1	Hip Impactor	2	Handle
1	Screwdriver	3	Total surface
1	Screwdriver	3	Extreme tip
1	Screwdriver	3	Internal tip/inside
1	Screwdriver	3	Handle
1	Reamer	4	Total surface
1	Reamer	4	Handle
1	Reamer	4	Ridged surface
1	Broach	5	Total surface
1	Broach	5	Tip
1	Broach	5	Inserted between/crevice
1	Broach	5	Spiked surface
1	Stryker System 6 Drill	6	Total surface
1	Stryker System 6 Drill	6	Internal drill head
1	Stryker System 6 Drill	6	Drill bit
1	Stryker Drill	7	Total surface
1	Stryker Drill	7	Drill head
1	Stryker Drill Bits with Handle	8	Total surface
1	Stryker Drill Bits with Handle	8	Under bit inside surface
1	Drill Key	9	Total surface
1	Scissors	10	Total surface
1	Scissors	10	Between blades
1	Clamp	11	Total surface
1	Clamp	11	Hinge
1	Clamp	11	Ridged clamp inner face
1	Rake	12	Total surface
1	Rake	12	Between teeth
2	Rongeur	13	Total surface
2	Rongeur	13	Grooves on tip
2	Rongeur	13	Inside connect point
2	Rongeur	13	Outside handle
2	Rongeur	13	Inside handle
2	Hammer	14	Total surface
2	Hammer	14	Head
2	Hammer	14	Outer handle
2	Hammer	14	Inner handle
2	Lombardi Atromatic Spreader	15	Total surface
2	Lombardi Atromatic Spreader	15	Spreader tip
2	Lombardi Atromatic Spreader	15	Hinge
2	Lombardi Atromatic Spreader	15	Handle and adjustable piece
2	Cobbs	16	Total surface
2	Cobbs	16	Handle
2	Cobbs	16	Tip
2	L-Shaped Spreader	17	Total surface
2	L-Shaped Spreader	17	Handle
2	L-Shaped Spreader	17	Tip
3	Long forcep	18	Total surface
3	Long forcep	18	Handle
3	Long forcep	18	Hinge
3	Long forcep	18	Serrated grip
3	Long rod	19	Total surface
3	Long rod	19	Looped end
3	Long rod	19	Rod shaft
3	Long rod	19	Handle
3	Graves (spreader/brace)	20	Total surface
3	Graves (spreader/brace)	20	Lock end
3	Graves (spreader/brace)	20	Clamp end
3	Larger rod with white handle	21	Total surface
3	Larger rod with white handle	21	Handle
3	Impactor	22	Total surface
3	Impactor	22	Shaft
3	Impactor	22	Rigid handle
3	Broach	23	Total surface
3	Reamer	24	Total surface
3	Reamer	24	Ridged surface
3	Reamer	24	Handle
3	Ridged reamer	25	Total surface

Results

Figure 1 shows a summary of log transformed RLU values of every swab taken from all sites and all instruments. The data is sorted from low to high RLU values and shown as a function of swab number.

Figure 1 –
All swab data collected for all instruments and all sites.

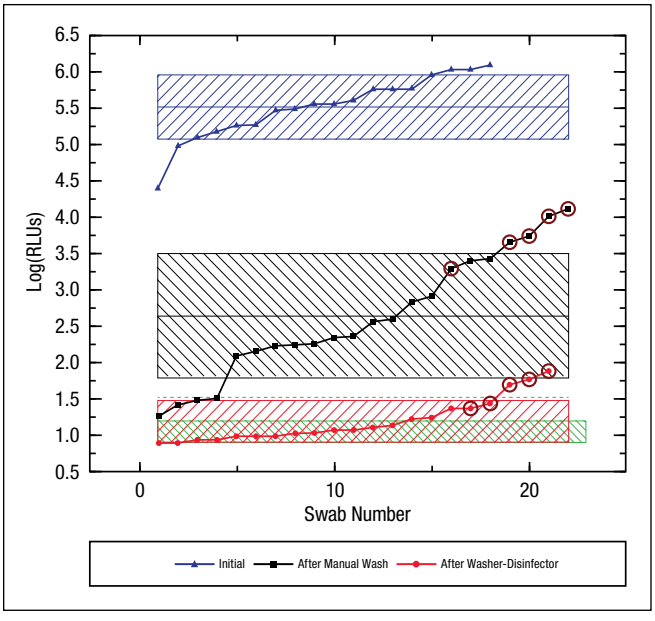


Swab number does not have any special meaning in the context of this analysis. The data for each step of the process was sorted from low to high Log(RLUs) to allow a better visualization of the results. As such, swab numbers do not identify the same instrument test point as you compare the data sets for each process step in Figures 1 and 2. The log transformed data in Figure 1 is color coded and sorted according to the step in the decontamination process at which testing took place. Blue triangles represent the values measured from swabs of instruments as received from surgery, prior to any washing. Black squares represent the values measured from swabs taken immediately after the initial manual wash step. Finally, the red circles represent values measured from instruments swabbed after completing a cycle in the washer-disinfector. The green triangles show the values collected from negative controls (swabs measured without ever removing them from their sleeve). Also shown on Figure 1, color coded to match the symbols, are shaded boxes representing the average value of all the swabs for that step in the process (solid line running through the middle of the box), and the corresponding ± 1 σstandard deviation (upper and lower boundaries of the shaded box).

Referring to Figure 1, we can see a statistically significant separation between average RLU values characterizing each step in the decontamination process. There is a two log reduction (2.37 ± 0.05) in the average RLU as a result of the initial manual wash process, followed by a further decrease of nearly two logs (1.78 ± 0.07) after the instruments complete the automated wash. After completing decontamination, the average RLU reading and the 1σerror bars associated with that value (1.14 ± 0.25) are slightly larger than the average RLU value and 1σerror bars of the negative controls (1.05 ± 0.16). Furthermore, we observe that the highest RLU values measured after completing decontamination (identified on Figure 1 by the brown open circles surrounding the red data points) were produced by the same instrument test points that also showed high values after the manual wash step (identified on Figure 1 by the brown open circles surrounding the black data points). Importantly, this observation implies that instruments carrying higher bioburden after manual washing will also emerge with higher bioburden after the automated wash.

Figure 2 shows a similar analysis for a smaller data set that includes only the swab used to sample as much of the total area of an instrument as possible (see step 3.b.i. in the protocol detailed above).

Figure 2 –
Data representing only a total swab per instrument.



Although the average RLU values are slightly different in this analysis versus the one that includes every swab taken, the same conclusions can be drawn:

- All steps of the decontamination process are separated by statistically significant decreases in the average RLU values
- The initial RLU reduction after manual washing is nearly three logs
- There is a further reduction of approximately 1.5 logs in RLU values after washer-disinfector cycle
- The RLU average values and 1 error bars characterizing instruments after completion of decontamination are higher than the negative controls
- Instruments that show the highest RLU values after the washer-disinfector cycle are also the same instruments that show elevated RLU values after manual washing.

Discussion

"You can't sterilize dirt" is an axiom often employed to signify the critical importance of properly decontaminating surgical instruments to achieve successful sterilization. There is some evidence in the clinical literature indicating that a certain percentage of surgical instruments processed through wash and disinfection are still contaminated[10]. This is largely because the primary method of assessing contaminated instruments relies on visual inspection. Using an ATP based assay to monitor residual soil on surgical instruments provides an objective, real-time method to assess and measure the level of cleanliness of these instruments, with significant advantages over methods based on the detection of residual protein. Furthermore, ATP based monitoring complements more traditional methods to determine the proper function of automated washer disinfector equipment (i.e. TOSI indicators) based primarily on verifying physical parameters (temperature and time) of a wash and disinfection cycle.

In this work, we were able to track the residual bioburden on 25 surgical instruments through each step of the decontamination process using the 3M™ Clean-Trace™ ATP system, at three different clinical sites. Based on the results, successful quality control of the decontamination process using this method appears to be highly feasible. The data also suggests that it is possible to use an objective method (similar to the one used in this research) to establish pass-caution-fail criterions in order to monitor cleanliness of surgical instruments on an ongoing basis. The method would consist of the following steps:

Step 1 –

Select the number of decontamination cycles (20–30 is typical) and the time period that will be used to generate benchmarking data.

Step 2 –

Select appropriate instruments

Suggestions:

- At least 3 instruments considered to be hard to clean

Step 3 –

For each cycle chosen in Step 1, sample and track instruments through each step in the decontamination process which can include but is not limited to steps prior to cleaning (e.g. receiving and inspection of instrument sets), pre-enzymatic/detergent soak, sonication, manual washing and processing through a washer-disinfector.

Step 4 –

Perform the following tasks after each step in the decontamination process making sure to sample chosen instrumentation by following the general swabbing instructions provided with the product:

- At each step in the decontamination process and before sampling test instruments, be sure to run a 3M™ Clean-Trace™ swab blank (no sample) to establish the background reading.
- Use 1 swab to sample as much of the entire surface of the instrument as possible.
- Be sure to note the type of instrument and area where swab samples are obtained so that the instrument can be sampled similarly as it progresses through decontamination.

Step 5 –

For each step of the decontamination process being monitored, use the data collected from Step 4 to determine an average Log(RLU) value and 1σ(standard deviation). For calculation of threshold values, one common approach would be to use the average +1σas the pass-caution threshold and the average +2σas the caution-fail threshold.

Statistically, following this procedure, as long as the process runs "in control" (i.e. as it did when it was benchmarked), 84% of tested instruments should have RLU values below the pass-caution threshold value, and 97.7% of tested instruments should have RLU values below the caution-fail threshold. Only 2.5% of the tested instruments would have a failing RLU value.

With the pass-caution-fail values determined from this procedure in place, test plans can be defined and results analyzed in the same manner in which ATP is currently used for patient room environmental monitoring. For example, if ten instruments were tested from a tray that just finished the automated wash cycle and more than 2–3 instruments failed, immediate intervention may be required. In addition, trending pass-fail numbers across cycles and time can be used to determine if the process is stable, getting better or worse, before deciding on intervention. The correlation between high bioburden at the end of manual washing and high bioburden at the end of the washer-disinfector cycle, stresses the importance of monitoring both steps. Furthermore, monitoring each step in the process is really the only way to fully diagnose where the problem is occurring.

Intervention could encompass several different actions:

- Stop and "quarantine" instrument tray or load
- Immediate reprocessing of instrument tray or entire load
- Verify wash-disinfector proper operation
- Audit and adjust process parameters
- Check activity of cleaners and replenish or replace
- Retrain operators on manual and automated operations

Finally, it is also possible to envision using the ATP system as a training tool, leveraging the real-time nature of the assay to provide immediate feedback to the Central Sterilization technician on manual and automated wash techniques and processes.

Conclusions

This paper demonstrates that ATP assays could be effectively used to monitor the cleanliness of surgical instruments throughout decontamination process. The assay provides objective, real-time data that is actionable in a variety of ways. We suggest a method to establish action limits that can serve as the cornerstone of a quality control process to monitor the process of decontamination. ATP based monitoring possesses clear advantages over protein based detection tools, and is clearly superior to visual inspection.

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