Uphill Grime: Process Improvement in Surgical Instrument Cleaning

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ABSTRACT

After its investigation of cross-contamination from arthroscopic shavers, the US Food and Drug Administration issued an alert to hospitals about medical device reprocessing methods. In response to this, a team of risk management and instrument room personnel at a university hospital undertook a project that tested the manufacturer's recommended cleaning methods for surgical instruments with the objective of determining the efficacy of automated instrument reprocessing and identifying a process that would produce a verifiably clean instrument after the cleaning process is performed. The quality improvement project focused on suction tips because they are used in most surgical procedures, are exposed to high levels of organic debris, and are difficult to clean. A variety of suction tips were cleaned and tested with a variety of processes and products to determine best instrument cleaning practices. Results of the project were eye-opening—debris was found where debris should not be, and the manufacturer's recommended cleaning methods—the current practices—were not effective. *AORN J* 96 (August 2012) 152-162. © AORN, Inc, 2012. http://dx.doi.org/10.1016/j.aorn.2012.03.018

Key words: *surgical instrument reprocessing, instrument sterilization, organic debris, perioperative safety, patient safety.*

Organic debris that remains in or on a surgical device is a threat to patient safety. In July of 2009, the US Food and Drug Administration (FDA) issued a Medication Devices Alert and Notice titled "Ongoing safety review of arthroscopic shavers."[1] The objective was to bring awareness to the possibility that tissue fragments or other debris can become lodged inside the lumens of surgical instruments, specifically arthroscopic shavers. The FDA recommended that health care personnel review their facility's instrument reprocessing procedures, both to ensure compliance with the operational guidelines of the manufacturers and to determine whether the recommended cleaning process actually yields the results necessary to ensure adequate sterilization, because what is not clean cannot be sterilized. Organic debris is persistent, and its elimination requires dedication of resources and collaboration among device manufacturers, medical professionals who use the instruments, instrument-specific cleaning process

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developers, and automated cleaning equipment designers.

INDUSTRY REPROCESSING STANDARDS

There are well-established industry standards for reprocessing a wide variety of surgical instruments (eg, scissors, forceps, needle drivers, arthroscopes, endoscopes, robotic surgery devices). These requirements include

- rinsing the devices shortly after use,
- soaking them in an approved enzymatic solution,
- hand-brushing or scrubbing the devices, and
- washing them in an automated reprocessor.

Various studies have attempted to verify the efficacy of cleaning methods in removing organic debris.[2,3] However, studies are often hindered by the

- variety of devices involved;
- variations in the shape, size, and composition of devices; and
- types of contaminants to which the devices are exposed.

Medical facilities use thousands of instruments every day, all of which are reprocessed and reused as patient demand dictates. To scrutinize the cleaning process for every type and variety of device would be highly impractical.

At our hospital, a multidisciplinary team consisting of personnel from risk management, infection control, and central sterile processing decided to respond to the FDA Alert by examining the reprocessing methods being used. Members of these departments regularly collaborate on patient safety issues such as this study. The team decided that a representative sampling of instruments would suffice. This sampling would control for the type of instrument evaluated, the cleaning and sterilization process used, and the types of debris encountered. Ultimately, we would objectively determine whether the cleaning processes were effective by looking inside the instruments for visible debris. If we saw something in the lumen of an instrument, we would determine what it was, which would allow us to gather data to develop conclusions regarding the potential harm and the effect on patient safety presented by residual debris remaining after the current cleaning process was complete.

FIRST-ROUND METHODOLOGY

After identifying the reprocessing methods that needed to be reviewed, who should do it, and how it should be done, the team assembled the components. These included personnel, equipment, instruments (ie, suction tips), and testing supplies.

Taskforce Design

Taking the needs of the patients, OR personnel, and instrument room staff members into account, we realized that a successful project would require an interdisciplinary effort. Members of the risk management, infection control, nursing, and central sterile processing departments collaborated. Each department provided a different component: personnel, expertise, help in procuring and handling instruments, and physical space for the testing. We asked applicable medical device manufacturer representatives to provide supplemental support, including a prototype reprocessor, and custom-made brushes in brass and stainless steel, and to collaborate in design and testing of these items. They complied willingly in recognition of the possible effect of the FDA's investigations on their industry. This cooperative networking and synergy established parameters for the project to help move it from planning to implementation of new processes. The parameters became our own specialized research and development program, working toward optimizing reprocessing and equipment methods through viewing the lumens, testing for debris, and adjusting the reprocessing continually.

Sample Selection

Striving for an ideal cleaning process, we decided to focus on instruments that would consistently

provide the maximum amount of debris after use compared with other instruments. After a brief survey of the instruments available for the project, we identified suction tips as a good candidate. Suction tips are available in a wide variety of shapes, angles, and sizes, and are exposed to all types of fluids, tissues, pathogens, and other contaminants. Typically, suction tips undergo a variety of both basic manual cleaning and ultrasonic cleaning according to manufacturer instructions. For this project, we selected suction tips from 12 instrument trays (each set containing 12 tips in four sizes) used for minor neurosurgery applications. All of the instruments in the selected sampling had visible contamination in their lumens.

Instrument Cleaning

The initial team investigation determined that the procedures followed in the instrument rooms at the hospital conformed to those recommended by the manufacturers' instructions. Instrument room personnel began the cleaning process with manual rinsing and brushing. They then soaked devices that remained visibly soiled in an enzymatic solution for 30 minutes. Finally, the instrument room personnel placed the suction tips in an automatic reprocessor and performed quality checks regularly and in accordance with manufacturers' specifications. Thus, instrument room personnel were meeting established industry requirements such that their practices would not be a contributing factor to the presence of residual organic debris.

Debris Visualization

For initial testing, the hospital team used a 3-mm digital video system. The video equipment (eg, camera, monitor) used for bronchoscopy procedures during the working week was briefly repurposed to explore the interiors of the suction tips in the first sample. Hereafter in this discussion, references to visible debris may be understood to mean not as seen by the naked eye but as magnified on a video screen when using this system or the fiber-optic camera system used in the continuing testing. The first round of testing was to determine whether debris was present, but no plans were made to assess it. When it became apparent that many suction tips contained debris, the second round was initiated.

FIRST-ROUND RESULTS

Central sterile processing and risk management personnel on the team performed preliminary testing to examine suction tips from the 12 neurosurgery trays, a total of 144 instruments. Manual rinsing and brushing removed the debris in 25% of the samples. They then soaked the remaining 75% (ie, 108 instruments) in an enzymatic solution for 30 minutes, after which another 10% were visibly free of debris. Next, they ran the suction tips through the automatic reprocessor. They ran the suction tips still showing organic debris (ie, 70 instruments [65%]) through as many as three cycles in the basic ultrasonic machine. Although each successive wash produced some positive results, at the end of three cycles, a number of suction tips were still visibly not clean as seen through the camera system (Table 1).

Although the attempt to reach 100% cleanliness was unsuccessful, this initial testing yielded considerable insight, including the following:

- Brushes used for cleaning must be available in a variety of sizes to accommodate the variations in size and type of suction tips.
- Many of the brushes were too soft and merely "tickled" the debris.
- After several cleaning attempts, the remaining organic debris is composed of several layers that are "packed" into the insides of the suction tips and require harder brushes (ie, steel wire).
- After each soaking/ultrasonic process, a brownish fluid would come out of the ends of the suction tips; whereas a clean suction tip would yield clean water. Whether the brownish fluid was caused by residue or debris, it should not have been present.

TABLE 1. Cleaning Protocol of the Initial Testing*

Cleaning protocol	Instruments with debris (%)
Taken directly from the inventory shelf (N = 144)	144 (100%)
After routine decontamination (N = 144)	108 (75%)
After additional soaking in 78% enzymatic solution for 20 minutes (N = 108)	70 (65%)
After undergoing an additional cycle in the ultrasonic machine (N = 70)	42 (60%)
After additional soak in and enzymatic solution for 20 minutes and 2 additional cycles in the ultrasonic machine (N = 42)	21 (50%)
After repeated soaking in an enzymatic solution for 20 minutes, 1 cycle in the ultrasonic machine, and rebrushing (N = 21)	17 (81%)
Soaked overnight in concentrated enzymatic solution (N = 17)	17 (100%)

** Based on established protocols from guidelines by manufacturers of both the instruments and the reprocessing machines.*

- Suction tips should be processed separately from other items because suction tips require more time for cleaning, should be packaged separately, and then added to trays; therefore, the facility's supply of suction tips needed to be increased to allow for the longer cleaning time.

SECOND-ROUND METHODOLOGY

Having determined in the first round of testing that there indeed was visible debris inside the lumens of the suction tips, our team decided that a second round of testing was needed to explore what the debris might be. Second-round testing added chemical testing methods and expanded on the number of instruments and the variations in washing methods.

Sample Selection

The second round of testing included suction tips from 36 surgical trays designed for a variety of specialized procedures. Instruments included

- two ear procedure trays;
- eight otolaryngology trays;
- two ear, nose, and throat microsurgery trays;
- two sinus endoscopy trays;
- four general neurosurgery trays;
- four "major" otolaryngology trays with instruments selected to serve for larger-scale procedures;
- one neck dissection set;
- two custom neurosurgical trays;
- three neurology microsurgery sets; and
- eight sets of scopes and debriders.

These trays offered instruments that were even more difficult to clean, including narrower and longer lumens, some with angles or narrowed features.

Instrument Cleaning

The second round of testing included a total of 350 instruments, a much larger sample than the first round. The suction tips that were hard to brush on the first attempt were soaked in a commercial enzymatic solution (ie, dilution 1 oz/gallon, according to manufacturer's specifications). Central sterile processing department personnel placed the suction tips in the reprocessor, ran them through two cycles, and brushed them again. This process was repeated two times. Each cleaning removed some of the contaminants; however, fewer than 5% of the suction tips were completely visibly cleaned at the end of the process (Table 2). The remaining 333 instruments (95%) were cleaner than they had been at the start but still contained debris.

We found two very specialized types of suction tips to be more difficult to clean because of their small diameter and design (ie, the suction catheter narrows as it gets closer to the tip of the instrument). To get a better look, the chief investigator cut one of these suction tips open lengthwise, thereby clearly illustrating the cleaning challenge that these tips present (Figure 1). At least four to five brushes of differing lengths and brush sizes were needed to clean the varying diameters contained inside one suction tip (Figure 2).

Even with the use of the different sizes, the brushes did not affect hardened debris. It became apparent that wire brushes (ie, brass, stainless steel, carbon steel, aluminum, wire tube) would be needed to clean these lumens. We realized that, if the best cleaning processes available did not yield suction tips free of residual debris, then different equipment, supplies, or procedures would be required to bring reprocessed instruments to the desired level of cleanliness.

To meet this need, the team focused on designing and assembling a new instrument-processing workstation. This workstation included

TABLE 2. Results From Phase II

Cleaning Protocol (N = 350)*	Instruments with foreign matter (%)†
Taken directly from the inventory shelf	350 (100%)
After routine decontamination	333 (95%)

** A total of 350 suction tips collected from 36 surgical trays.*
† Detectable debris was present in most instruments even after decontamination.

- a new model of an automated instrument washer using
  - a combination of digital ultrasonic energy,
  - enzymatic solution seeding of lumens,
  - dwell time within those lumens,
  - multiple air-injected solution flushes, and
  - high-temperature rinse and flush;
- a space for manual cleaning;
- additional room for residual testing of the cleaning process; and
- detailed visual survey equipment consisting of a fiber-optic digital video camera system to look inside the instruments.

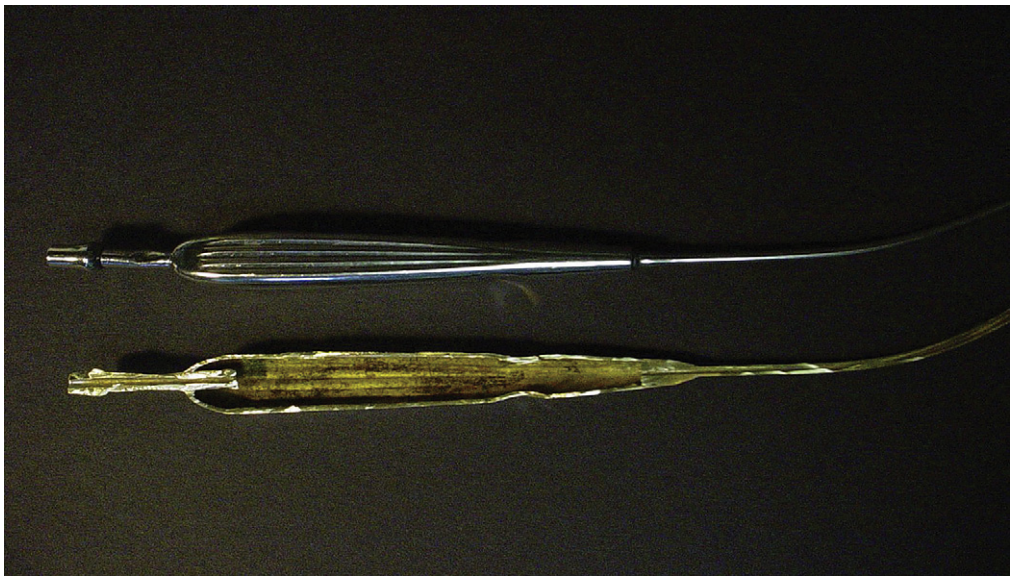

Figure 1. Interior of a Yankauer suction tip cut open length-wise demonstrating evidence of the cleaning challenge presented.

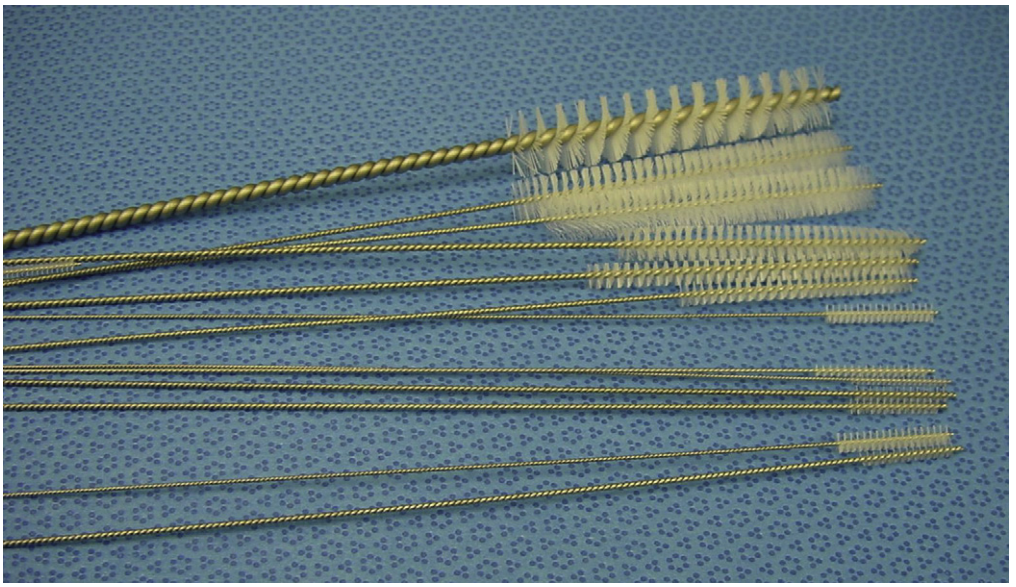

Figure 2. A selection of cleaning brushes, demonstrating the widely varying sizes required to reach inside instrument lumens.

Both the automated reprocessor and the fiber-optic camera system were offered on loan for a limited time from the manufacturer and the distributor, respectively. A small area for a workstation was set aside in the instrument room of the central sterile processing department that would accommodate all the equipment and personnel. Building maintenance engineers installed upgraded power lines and plumbing, and the workstation was ready for use.

Debris Visualization

For this stage of testing, the team used a higher-resolution and more effective fiber-optic video camera and brushes made of brass or stainless steel. Brushes with the desired handle length were not commercially available, but arrangements were made to procure a supply of prototypes and special-order brushes from the manufacturer. Specifications for these brushes included

- 16-inch length,
- 3/4-inch diameter finger loop (used to hold the brush),
- sizes ranging from 2 mm to 7 mm, and
- a bristle length of 0.79 inches.

Finally, because the shafts of many lumens narrow toward the tip, team members used brushes in descending sizes to achieve optimal manual cleaning.

Debris Assessment

The final component necessary for the second round of testing was a method to assess the level of organic residue present after each stage of the cleaning process. To obtain the greatest amount of useful information, two methods were used to assess debris in the lumens:

- a test featuring a long, narrow swab that would fit inside the suction tips being tested and indicate the presence of adenosine triphosphate (ATP)[3,4] (ie, the signature compound of all living cells, including plants, animals, molds, and bacteria) and
- a test-strip system using sterile water flushed through the suction tip that indicates the presence of blood, protein, and carbohydrate.

Adenosine triphosphate testing is a standard marker for organic materials, widely used to

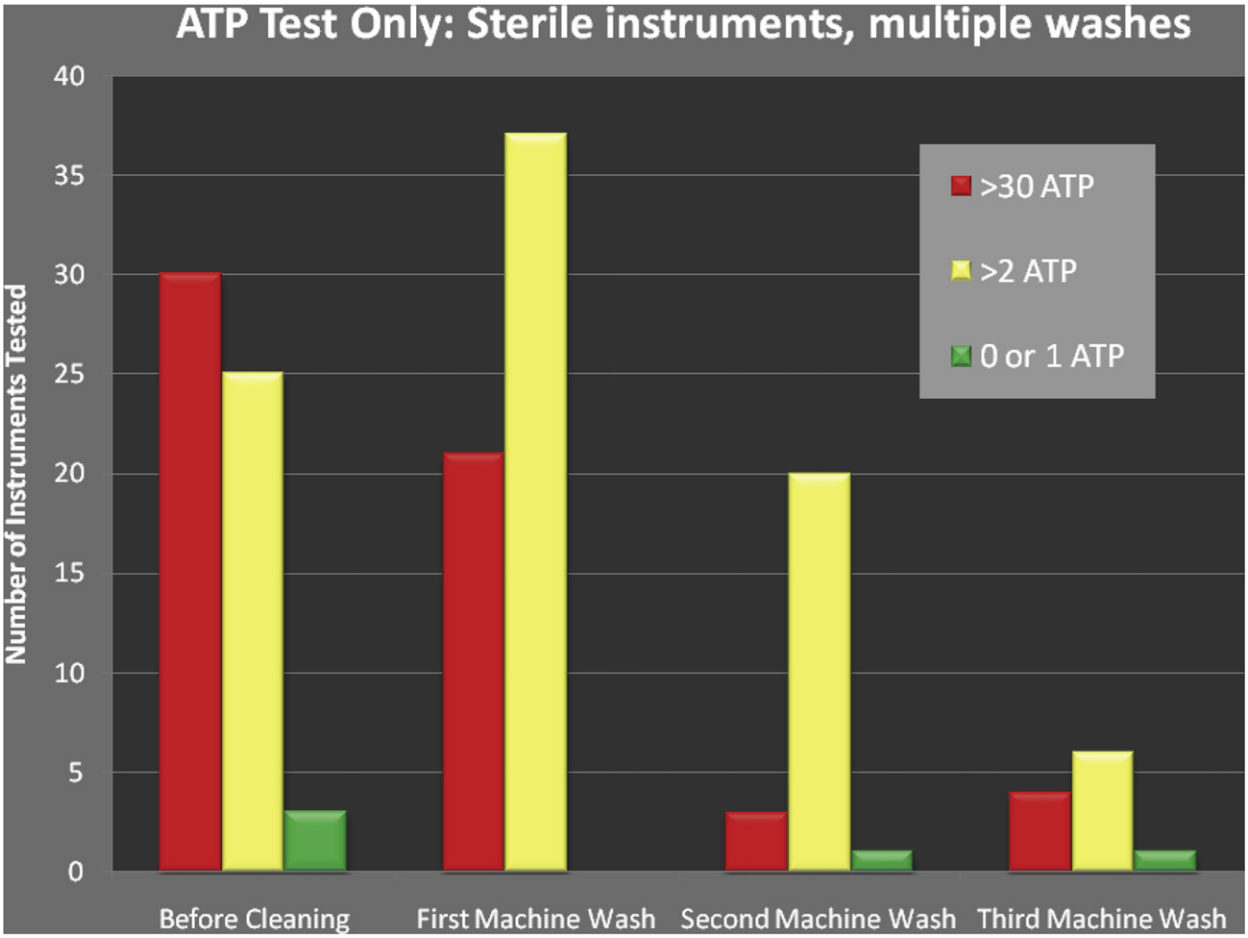

Figure 3. Phase II testing used instruments taken from reprocessed (patient-ready) surgical trays. As instruments reached an acceptable level of cleanliness, they were removed from the sample.

test for contamination in wastewater treatment, manufacturing processes, and the food service industry. This testing method uses a bioluminescent marker, luciferase, which is measured in relative light units (RLUs). In the food industry, a reading of fewer than 10 RLUs is considered clean for use. A reading of 30 RLUs is considered contaminated.

The test-strip system is a commercial product designed specifically to check instrument reprocessing. Sterile water is injected into the instrument lumen and collected in a sample cup. A test strip is then introduced into the cup and changes in its coloration prove that trace amounts of hemoglobin, protein, or carbohydrate have been detected. Both test methods provide results within a few seconds and indicate the presence of any detectable biological residue, thereby proving the efficacy of the cleaning methods being used.

SECOND-ROUND RESULTS

Testing on the new workstation began with extra suction tips that were saved overnight from surgical procedures performed the day before so that the maximum amount of dried-on debris would be present. Questions arose regarding whether testing should be performed with actual, patient-used instruments, or with instruments tainted with artificial test soil. Some team members reasoned that artificial test soil would provide a more controlled, scientific sampling. However, this would have required purchasing new instruments not previously contaminated from actual use. With an ample

supply of soiled suction tips already on hand, the team decided to proceed with testing instruments contaminated with debris from actual use.

Experimentation continued until testing supplies were depleted and a suitable amount of data had been recorded. Numerical data were obtained through the ATP testing. With respect to testing the channels for protein, hemoglobin, and carbohydrate, results were either positive or negative. The visual check with the 3-mm camera provided direct observation of the cleaning process's success or failure. Results proved to be surprising and thought provoking.

CONCLUSIONS AND RECOMMENDATIONS

As expected, soil levels were reduced in many instruments after both manual and mechanical cleaning through the new suction tube-specific automatic wash process. In some instruments tested, however, measurable organic debris, as indicated by RLUs, actually increased after cleaning (Figures 3 and 4), which means that, although overall debris levels dropped, the number of instruments showing some residual debris after cleaning went up. This was explained because, as the project progressed, we discovered that the improved cleaning process had dislodged and rehydrated residue that had not previously been removed because it had been baked onto the surface of the instrument. Repeated cleanings were required for these instruments. Some instruments never reached an acceptable level of cleanliness. This information caused the university hospital procurement personnel to replace approximately 10% of the suction tips much sooner than had been planned.

Use of the new, metal brushes not only exposed the earlier layers of debris but also raised questions

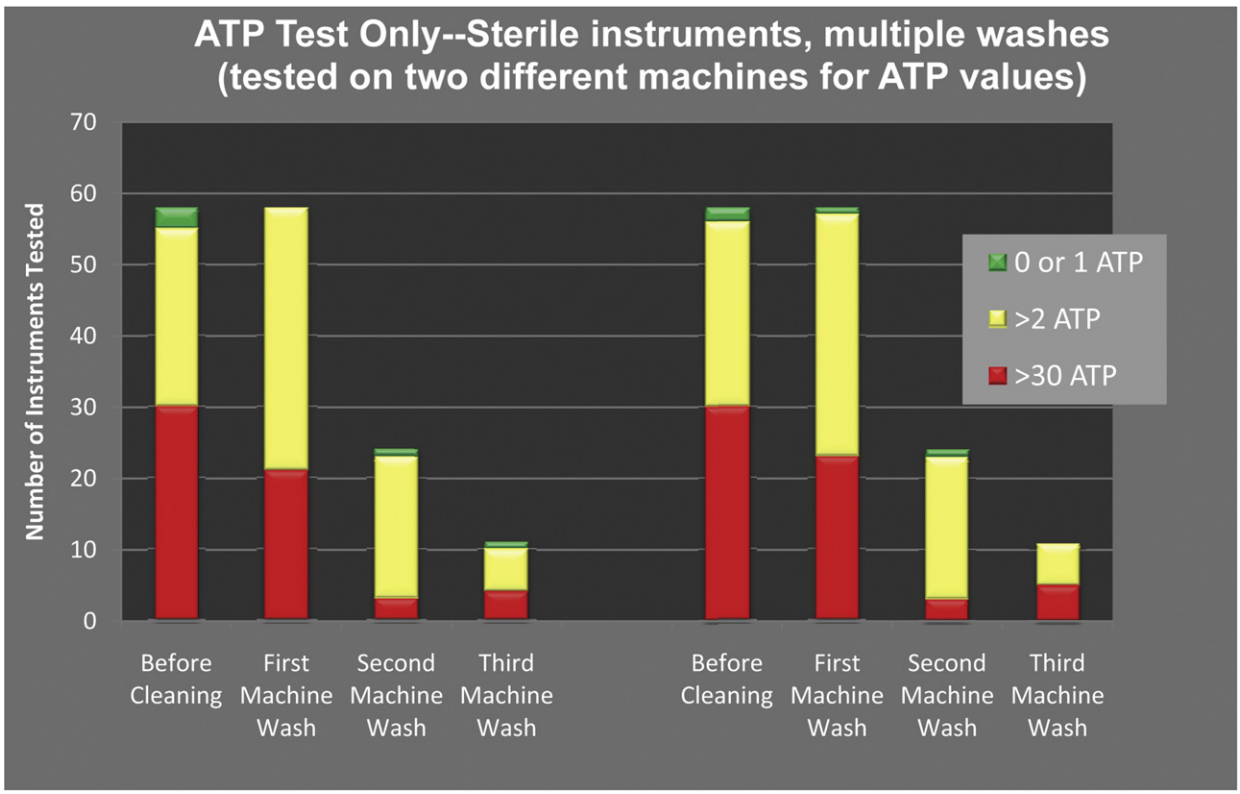

Figure 4. To ensure that testing equipment was accurate, selections of instruments were tested by using two different adenosine triphosphate (ATP)-detecting apparatus. The similarity of the results suggests that the testing is accurate.

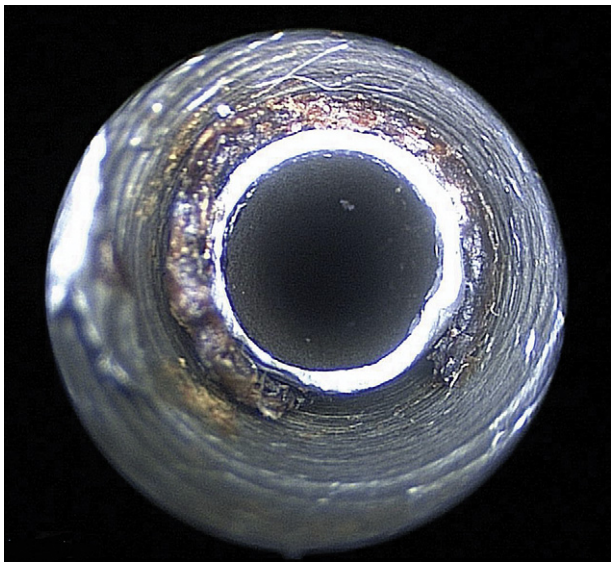

Figure 5. Visible organic debris inside a Frazier suction tip selected from an instrument tray that had already been processed and was ready for its next use.

as to the composition of the instruments. Review of the product manuals demonstrated that the instruments were mainly composed of stainless steel or machined aluminum; both materials are resistant to rust and corrosion. However, examination of the

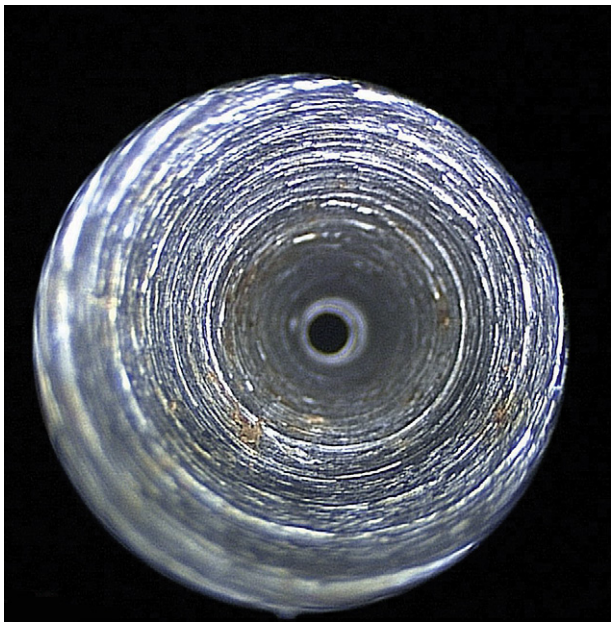

Figure 6. The unpolished interior surface of suction tips allow debris to adhere to the inside.

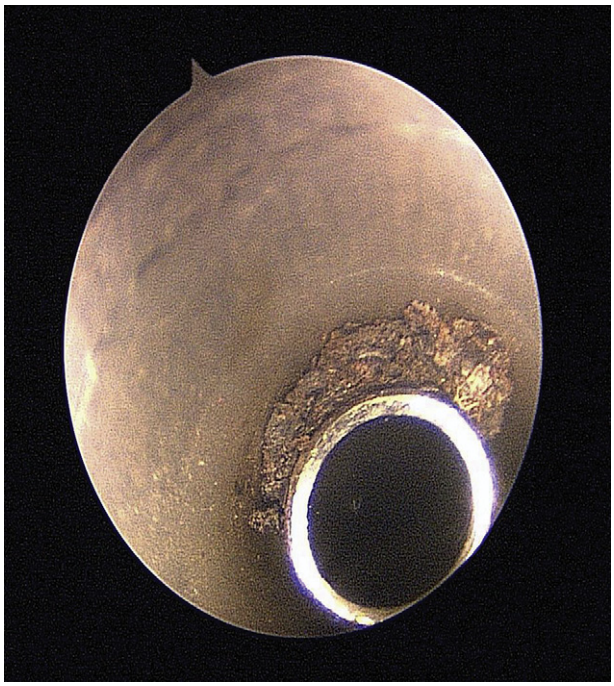

Figure 7. Manufacturing defects such as this weld can result in an accumulation of debris at this point in the suction tip, which can be impossible to clean.

interiors showed the presences of welds, ridges, grooves, and other tooling marks that seemed to contribute to the build-up of contaminants (Figures 5, 6, and 7). Some team members worried that using metal brushes, while effective in removing reachable debris, might contribute to the degradation of the interior surfaces by creating rough spots even more susceptible to the accumulation of clinging material, thereby shortening the useful life of the instrument.

Team members worked on comparing the ATP results and the hemoglobin-protein-carbohydrate test, and on comparing manual and machine washing results (Figure 8). We considered the possibility of false positives or cross-contamination, and whether both tests were necessary. The consensus was that unacceptable debris would not be indicated by ATP or hemoglobin alone. For this reason, the data gathered by using both testing methods provided more useful information on the level of cleaning needed and on the expected target of cleaning (ie, debris or biofilm present) for the individual

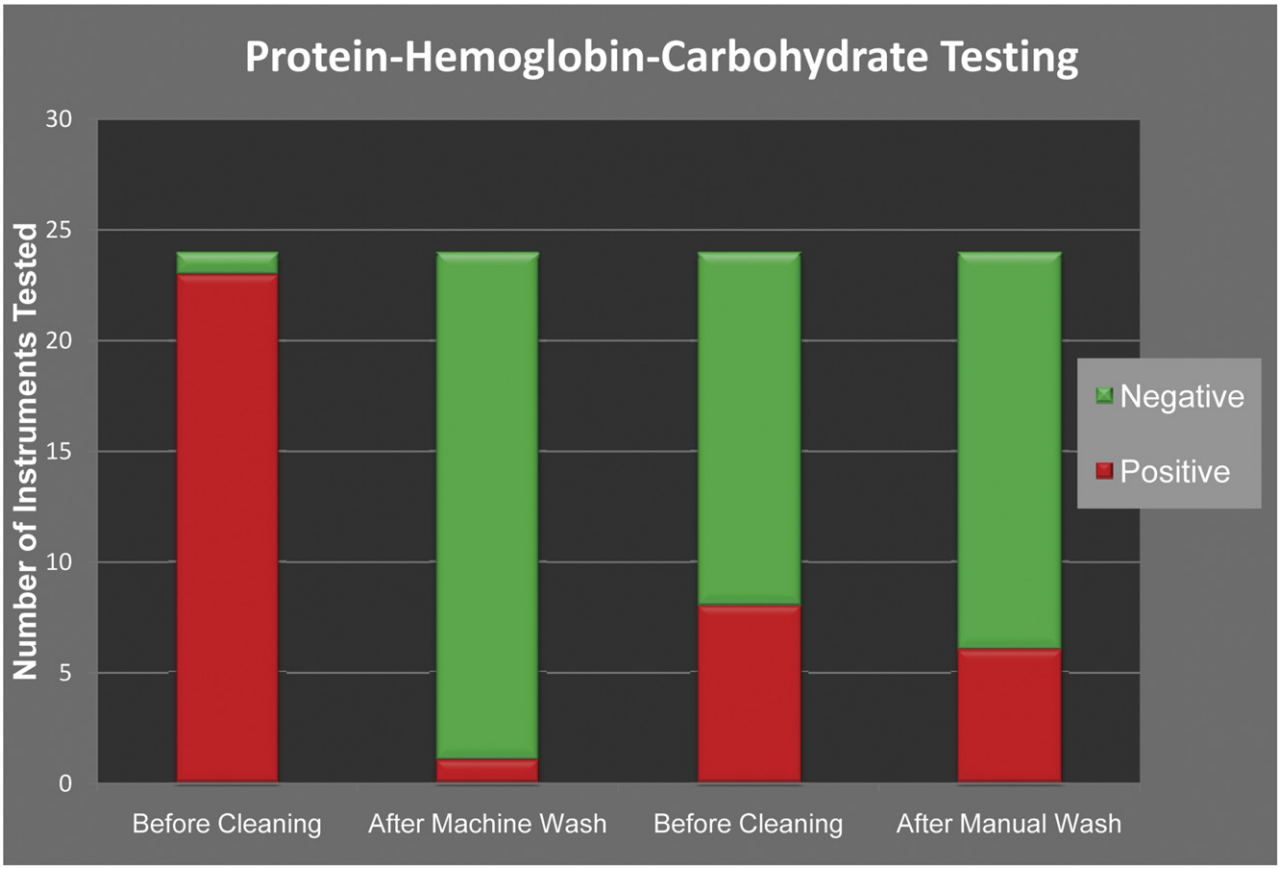

Figure 8. Comparison of the results of the hemoglobin-protein-carbohydrate test between machine washing and manual washing.

tests used (eg, ATP, protein). A properly cleaned instrument would ideally have ATP at or near zero and would be negative for hemoglobin-protein-carbohydrate.

The test results answered the clinical question that initiated this project: the increasing sophistication of medical instruments has resulted in instruments that may be impossible to clean with current technology. For many years, the answer to the presence of biological debris was to lay blame on those team members responsible for cleaning the instruments. However, this project demonstrated that even ideal cleaning processes can leave contaminants behind. Four questions remain:

- Are retooled instruments needed?
- Should revised cleaning techniques be implemented?
- Should the cleaning method be more fully automated to ensure consistent and repeatable results?
- What enzymatic solution or combination of solutions will help solve this debris problem?

Surgical instruments that cannot be thoroughly cleaned of debris cannot then be sterilized effectively for patient use. As instruments become more complex, cleaning processes necessarily become more complex as well. Determining the best means of cleaning instruments is vital to ensuring patient safety. A reliable process will help protect against surgical site infections and reduce any possibility of cross-contamination. Individual health care facilities, the FDA, and other entities must continue to study and address the challenge presented by instrument cleaning. This project revealed that,

often the instruments are not thoroughly cleaned even though personnel follow manufacturer instructions, but the solution to this problem, as well as its significance, requires additional investigation. AORN

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