Quantitative Analysis and Verification of Acceptance Thresholds for Residual Protein in Cleaning of Reusable Medical Devices

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Introduction

- Cleanability and measures of cleaning have become high-visibility issues for reusable medical devices.
- Knowledge of real-world data for evaluation of achievable levels of soil in SPD's is critical for setting expectations and benchmarking each facility's operations relative to the current state of the art.
- This study reports on real-world evaluations of cleaning efficacy for nearly 9,000 instruments at healthcare institutions throughout Europe.
  - This study did not include flexible endoscopic instruments or explicitly include robotic instruments, which present a different array of challenges.

Instruments Studied

- The studies were carried out by SMP GmbH, Miele & Cie., KG, and MMM GmbH

- Laboratory Test Instruments: 4,122 Crile Clamps inoculated with sterile sheep blood[1]
- Real-World Test Instruments
  - 3,780 Jointed Surgical Instruments of multiple specific types
  - 786 Minimally-Invasive Instruments
  - 288 Ophthalmologic Instruments

- These investigations were done as part of annual revalidation of the washer disinfectors, as well as specifically for this study

1: Per the German Guidelines for Annual Minimum Tests of Washer-Disinfector Cleaning Efficacy, DGKH, DGSV and AKI

Testing Methodology

- Washing was done using detergents with use alkalinity of > pH 10.
- The wash phase was 10 minutes in over 85% of the cleaning tests.
- The water used for the washing process was demineralized water in over 85% of the facilities where testing was done.
- The washers' function (water pressure, spray arm function) was verified prior to testing.
- Residual protein elution was carried out using a 1% sodium dodecyl sulfate solution.
- Laboratory protein analysis was done using the OPA spectrometric method.
- Residual protein analysis was carried out using the BCA or OPA methods if evaluation was done on site.

Details of Laboratory Analysis: Elution of Residual Protein

- Tested instruments are removed from the washer-disinfector before the thermal disinfection phase, to not denature the proteins and make them undetectable.
- For crile clamps, the clamp is placed into a test tube, and the previously-inoculated box lock is irrigated with 2 ml of 1% SDS solution that is captured in the bottom of the test tube for spectrophotometric analysis.
  - The tube may be inclined to expose the inoculated surface to the SDS solution for a longer elution period. Agitation or sonication may be used to improve the removal of residual protein.
- For real-world instruments, a similar elution method is used, with the quantity of eluant modified to ensure that all soiled surfaces are eluted. Elution is done for a time adequate to remove all accessible protein.

Results

Instruments→ Residual Protein Level ↓	Crile Clamps	Everyday Surgical Instruments	MIS Instruments	Ophthalmologic Instruments
Too low to detect	73%	64%	86%	90%
Tier 1	20%	18%	7%	6%
Tier 2	4%	6%	5%	1%
Tier 3	2%	12%	2%	2%
Tier 4	N/A	N/A	<1%	1%

Definition of Tiers of Residual Protein

Instruments→ Residual Protein Level ↓	Crile Clamps	Everyday Surgical Instruments	Ophthalmologic Instruments	MIS Instruments
Tier 1	<50 µg			<20 µg
Tier 2	50-75 µg			20-50 µg
Tier 3	75-100 µg			50-100 µg
Tier 4	N/A		>100 µg	> 100 µg

Outliers

- Of all the instruments tested, only the MIS and Ophthalmologic instruments had any examples with a total residual protein load of >100 µg.
  - Two trocar sleeves showed values of 156 and 175 µg, which are less than half of the currently-accepted US threshold value of 6.4 µg/cm^2 but at or above the German acceptance criterion of 3.0 µg/cm^2.
  - Ophthalmologic instruments had more outliers, percentagewise. Given their generally small surface area, this indicates an issue with design for cleanability in certain examples more than with cleaning.

Comparison to 2005 Round-Robin Study

2005 Round-Robin Results[2]

- Acceptance threshold limit for Crile Clamps: 100 µg/instrument.

Current Study Results and Proposal

- Acceptance threshold limit for Crile Clamps: 80 µg/instrument.
  - The state of the art for cleaning has improved to where only 2% of the tested clamps had residual protein in excess of 75 µg-the bar can be raised, and patient safety improved.

"Round-Robin Study of Validation of the Minimum Cleaning Performance Following the Guidelines of the DGKH, DGSV, and AKI," K. Roth and W. Michels, Zentral Sterilisation 2005:13, 106-116

Discussion

- This study demonstrates that the achievable level of residual protein is generally low. On average, healthcare cleaning results have significantly improved since our 2005 study.
  - This can be improved further by performing routine validation of the washing process.
- Levels of acceptable residual protein per instrument should be normalized to the surface area and complexity of the instrument, since:
  - Size does matter; you can't compare a small ophthalmologic instrument to a flexible endoscope, and,
  - Elution of residual protein for analysis depends strongly upon instrument design and the ways available to access its soiled surfaces.
- To our knowledge, no similar studies have been published using enzyme detergents.

Conclusions

- The state of the art of cleaning of reusable medical devices has improved over the period 2005-2013.
- Lower acceptance limit thresholds may be instituted for most instrument types than previously permitted.
- Due to limitations in measurement technology, with the limits of detection being approached in many situations, the next step in improvement of instrument cleaning for many instrument types is redesign for cleanability.
- Routine verification or, preferably, validation of the cleaning process per ISO 15883 is essential to maintain the current levels and, potentially, decrease them, improving patient safety.

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- Note: Quality Processing Resource Group is a joint venture partnership between the companies of the four persons above designed to provide the voice of SPD to medical device manufacturers and the voice of medical device manufacturers to the SPD. It will become the AAMI presence of all of the above groups as of next fall's Sterilization Standards meeting