



Smith, A., Winter, S., Lappin, D., Sherriff, A., McIvor, I., Philp, P., Suttner, N., Holmes, S. and Stewart, A. (2018) Reducing the risk of iatrogenic Creutzfeldt–Jakob disease by improving the cleaning of neurosurgical instruments. *Journal of Hospital Infection*, 100(3), e70-e76.

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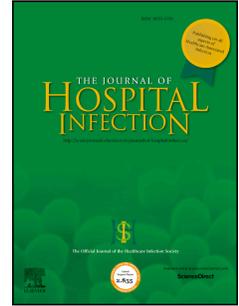
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# Accepted Manuscript

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PII: S0195-6701(18)30139-7

DOI: [10.1016/j.jhin.2018.03.001](https://doi.org/10.1016/j.jhin.2018.03.001)

Reference: YJHIN 5361

To appear in: *Journal of Hospital Infection*

Received Date: 5 January 2018

Accepted Date: 1 March 2018

Please cite this article as: Smith A, Winter S, Lappin D, Sherriff A, McIvor I, Philp P, Suttner N, Holmes S, Stewart A, Reducing the risk of iatrogenic CJD by improving the cleaning of neurosurgical instruments, *Journal of Hospital Infection* (2018), doi: 10.1016/j.jhin.2018.03.001.

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**Reducing the risk of iatrogenic CJD by improving the cleaning of neurosurgical instruments**

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**Summary**

**Background:** Currently UK vCJD cases total 178, with an estimated maximum 1:2,000 carriage rate based on archived appendix and tonsil tissue, implying infection maybe rare but carriage relatively common. Previous workers have identified that maintenance of surgical instruments in a humid atmosphere after use and prior to cleaning assists cleaning efficacy. Relatively recently the Department of Health/Advisory Committee on Dangerous Pathogens UK have recommended a surgical instrument cleanliness threshold post cleaning of <5µg protein per instrument side.

**Aim:** Quantitate cleanliness of neurosurgical instruments and investigate cost-effective measures for improved cleaning.

**Methods:** Two instrument protein quantitation methods were used. One based on the International Standard (15883 series) using sodium dodecyl sulphate (SDS) elution and orthophthalaldehyde (OPA) reaction and a second in-situ protein fluorescence detection system (ProReveal) providing results per instrument side. In vitro investigation of the efficacy of some commercial and in-house pre-clean wetting agents was undertaken using artificial test soil and stainless steel discs under standard conditions. In vivo evaluation of best performing in vitro agents was undertaken on craniotomy sets.

**Findings:** Residual protein levels using ProReveal technology demonstrated that 163/187 (87%) of neurosurgical instruments were <5µg protein/instrument side. The use of proprietary NHS plastic bags and sterile water soaked wound pads were equivalent in efficacy to commercial pre-cleaning wetting products and significantly less expensive.

**Conclusion:** Although we demonstrate low in situ protein levels on neurosurgical instruments and the beneficial effects of keeping instruments moist, other cleaning critical control points such as instrument loading patterns should also be monitored.

**Key words:** CJD, pre-cleaning, cleaning, risk reduction, neurosurgical instruments, automated washer-disinfector.

## Introduction

Although most of the UK population was exposed to BSE largely between the early 1980's – mid 1990's, symptomatic cases of vCJD have remained rare. There have been 178 cases in the UK (1) and in terms of iatrogenic CJD linked to medical devices there have been six instances reported Worldwide (2). However, results of three major appendix surveys carried out to date all show prevalence of abnormal prion protein in the UK population to be around 1 in 2,000 – 1 in 5,000 (3-5). Implying infection maybe rare but carriage relatively common. Prions are very difficult to inactivate and infectivity can survive steam sterilization at 134°C(6). With variant CJD (vCJD), there are particular concerns about potential spread from central nervous system (CNS) and lymphatic tissue. Within Scotland steps have been taken to reduce the risks of vCJD transmission by improving the decontamination of reusable surgical instruments (7-9). Risk assessments have emphasized the importance of cleaning surgical instruments prior to sterilization and high carriage rates emphasise the continued role of risk reduction strategies (5,10). Previous workers have demonstrated the importance of maintaining surgical instruments in a moist state prior to loading into a wash process (11,12).

The aim of this study was to investigate processes to improve the cleaning of neurosurgical instruments by quantitating residual protein levels on washed instruments, which pre-cleaning treatment methods are efficacious and cost- effective and whether quantitative protein estimation methods can be used to quality control neurosurgical instrument cleaning.

## Methods

### Neurosurgical instruments and set selection

The 5 most commonly used sets of neurosurgical instruments in NHS Greater Glasgow & Clyde and the 5 most common supplementary items were selected for study. Within each set the project group agreed to assay a minimum of 5 different instruments that were most frequently used during an operation linked to a specific set of instruments. Frequency of use based on clinical experience of the project group Neurosurgeon (NS) and Neurology Theatre Co-ordinator (PP). Details of sets, instruments and supplementals are summarised in supplemental Table Ia & Ib, where opportunity arose additional instruments were included. Assays for residual protein levels were undertaken on used instruments prior to cleaning and following cleaning in an automated washer disinfectant.

**Neurosurgical theatre instrument preparation following use, transportation and wash process.**

During use neurosurgical instruments are manually wiped clean as per theatre standard operating practice. On completion of the operation and determination of set integrity, trays are wrapped in a proprietary NHS clear plastic bag and placed in a wheeled buggy for uplift and transport to the Sterile Service Department (SSD), Cowlairs. In the Wash room at the SSD instruments are removed from the theatre tray and loaded into washer baskets and placed in the automated washer disinfectant (AWD) (Supplemental figure 1).

The automated washer disinfectant (AWD) used throughout this study was a Getinge model CM310 using detergent Metal Clean (pH 13.1). The instruments are exposed to 4 phases of an automated wash process in 4 different chambers. Chamber 1: prewash with mains water at 30°C for 8 minutes, wash with mains water at 55°C for 10 minutes with 6ml detergent/1 litre of mains water followed by chamber 2: Mains water rinse for 5 minutes followed by reverse osmosis (RO) water rinse at 90°C for 1 minute followed by chambers 3 and 4 hot air drying for 15 minutes each. Total cycle time (including heat up and cool down is 55 minutes). Each AWD undergoes an annual performance qualification test using a standard load, soiled with Edinburgh test soil and cleaning efficacy assessed visually and swabbing with a protein detection swab (3M protein trace).

**Protein assays****SDS extraction and Orthophthalaldehyde (OPA) method**

This method was based on that described in the ISO 15883 standard (13-15) and previous workers (16,17). Briefly, the instrument was placed in a polythene bag and after addition of 5 or 10ml (depending on size of instrument) of 1% Sodium Dodecyl Sulphate (SDS), the bag was agitated by hand over a period of 30 mins to ensure that the SDS solution was able to access all surfaces. Aliquots of eluent were assayed using OPA solution in triplicate. A bovine serum albumin (BSA, Sigma) standard curve and blank controls were run with each assay. The limit of detection was 3µg protein/ml (30 µg protein/instrument if 10ml elution volume used).

**In-situ analysis of residual protein using OPA (ProReveal)**

This method was based on the manufacturer's instructions (Synoptics Ltd, Cambridge) for the ProReveal technology (GBox EF2 with ProReveal software). The ProReveal test consists of a reagent based on an OPA fluorescent spray, which reacts with protein residues left on

instruments without the requirement for an elution stage (18). A similar number of replicates was undertaken using the ProReveal system to quantitate and locate residues of protein on instruments. Calibration of the ProReveal equipment was undertaken using BSA standard curves. The limit of detection was 50ng protein/cm<sup>2</sup> instrument surface. For both assays, sets of new unused surgical scissors but cleaned using the same AWD process was used as a negative control.

### **In vitro assessment of pre-cleaning solutions**

This was undertaken by applying Edinburgh Test Soil (made-up in house according to specification in TS/ISO 15883-5 (15)) to stainless steel discs. 10 µl of Edinburgh test soil (3.4 µg protein) were applied to 24 stainless steel (316 stainless steel, mirror finish) discs (1 cm diameter) in a 24 well plate (Costar, ThermoScientific) and allowed to air dry overnight. This stage was introduced to provide a worse case scenario for soil drying onto instruments during prolonged theatre cases. The plate was then transferred into a sealable bag (zip-lock, Tesco, UK) and the “wetting agent” was applied according to manufacturer’s instructions and left for 80 min (time determined as worst case scenario for period during which “wetting agent” would be in contact with instruments from preliminary studies). This was followed by a standardized washing step on a motorized rocking platform (Grant Bio PMR 32 Rocker set at 20 tilts per minute at room temperature). Each well containing a soiled disc was then exposed to 2 ml of 1% SDS for 5 minutes (time exposure based on validation work using different time points, data not shown) following which the disc was removed and residual protein levels assayed using ProReveal technology. Each test condition was undertaken with x3 discs and assayed in triplicate. A “bag control” with soiled discs in a plastic bag without wetting agent as well as a control without bag or wetting agent was included for each experiment.

### **Pre-cleaning solutions investigated**

Preliminary investigations (data not shown) had demonstrated that equivalent humidity levels were obtained in standard NHS plastics bags compared to commercially available plastic bags. The NHS bags were used subsequently for all further experiments. The wetting agents assessed included Prezyme (Ruhoff Corporation, 393 Sagamore Avenue, Mineola, NY, USA), Foreverwet (Ruhof), Pre-Klenz transport gel (Steris Corporation 5960 Heisley Road, Mentor, OH, USA), Neozyme (Medimark Scientific Ltd, P. O. Box 573, Sevenoaks, Kent

TN13 9RQ, United Kingdom) and sterile water on an absorbent pad (NHS wound pads - 40x20cms).

### **In vivo assessment of best performing pre-cleaning solutions**

The best performing wetting agents from the in-vitro study i.e., Steris Pre-Klenz and sterile water/pad plus the proprietary NHS theatres clear plastic bag (610x760mm) were investigated in-vivo as part of a clinical trial of different wetting agents. For the purposes of the trial, the most frequently used set (Craniotomy set) was investigated, from which the Adsons elevator was selected as a process challenge instrument coated with Edinburgh test soil (15).

Efficacy of pre-cleaning solutions was assessed using two different soiling methods; a. Native soil: Instruments from craniotomy sets were assayed for residual protein after use and exposed to either Steris Pre-Klenz wetting agent or sterile water/pad both enclosed using the same NHS proprietary clear plastic bag. b. Artificially soiled difficult to clean instruments: Two process challenge instruments (Adson elevators) were added to each craniotomy set after soiling with Edinburgh Test soil. The duration of drying of Edinburgh test soil was based on data derived from instrument set waiting times between theatre operation completion and wash process at Cowlairs SSD. The artificially soiled Adson elevators were added to craniotomy sets (in duplicate) at the SSD wash-room and loaded into the AWD alongside the instruments with native soil. These acted as “indicator” instruments to assess the feasibility of using a process challenge instrument from a nominated instrument set to provide an indicator of cleanliness without holding back the progress of the set through the decontamination process. Following use in theatres, a craniotomy set was prepared for transportation using the wetting agent. Each wetting agent was applied for a consecutive series of 10 trays. On arrival in the SSD the tray was identified and the “indicator” instruments included in the same wash basket as the craniotomy set. Following the wash process the craniotomy instruments were assayed using the in-situ OPA assay for residual protein content as previously described.

### **Estimate of instrument surface area**

In order, to capture surface area data from our study instruments we developed a method to calculate the 2-D surface area of the instruments we have assayed by photographing, digitalizing and outlining the area of the instrument. All instruments were imaged using a digital camera positioned analogously to their position during protein-detection test using

ProReveal against a scale (cm). Software (ImageJ ver. 1.8) was used to trace the edges of each instrument and the outlined area measured to provide an approximate instrument surface area in cm<sup>2</sup>.

### **Statistical analysis**

SPSS statistics software (IBM, Chicago USA) was used for statistical analyses. For research question “which pre-cleaning treatment methods are most efficacious”, the in-vitro data was plotted in Microsoft Excel, to compare performance based on residual protein levels and analysis was performed on log-transformed data using ANOVA and a Tukey post-test. For research question “which pre-cleaning treatment methods are most efficacious”, the in vivo results of cleaned instruments without pre-treatment were compared with results after pre-treatment 1 (Steris PreKlenz) and pre-treatment 2 (Sterile water), using log transformed data and ANOVA and Tukey post-test.

### **Results**

#### **Quantitative analysis of protein residues on neurosurgical instruments**

During the course of this investigation we assayed over a 1,000 neurosurgical instruments, the breakdown of instruments assayed (excluding periosteal elevators) is summarised in Supplemental Table II. An example of residual protein detected on a McKissock Dural scissors is shown in Supplemental Figure 2. Details of protein levels on instruments from the different neurosurgical sets are found in Supplemental Tables III-XIV. The distribution of individual instrument protein levels using the ProReveal method is summarised in Figure 1. In-vitro residual protein level results for all wetting agents tested and controls were assayed after 5 minutes cleaning under standard conditions (rocking platform and 1% SDS solution at room temperature). Results are summarised in Table 1. Steris Pre-Klenz and Sterile Water show significantly cleaner results ( $p < 0.001$ ) when compared to discs with no bag and no wetting agent.

#### **In-vivo results**

There were two arms to this investigation that determined the effect of the Steris wetting agent or sterile water/pad on cleaning efficacy. Each wetting agent was tested on 10 consecutive craniotomy trays. From each tray, eight different instruments were assayed for residual native soil. In addition, each tray processed had two artificially soiled Adson elevators, included to test the efficacy of the wash process. For both the Steris wetting agent and sterile water pretreated instruments the residual protein on instruments was below the

limit of detection for the OPA assay (30 µg/instrument) this was significantly lower ( $p < 0.0001$ ) than that for the untreated craniotomy sets (Supplemental table XV). The addition of the elevator instrument artificially soiled with Edinburgh test soil as a process challenge device also proved a useful addition to each set and residual soil levels were below the limit of detection for this challenge. Residual protein levels were significantly lower after cleaning of wetting agent pre-treated instruments. There was no significant difference between the wetting agents Steris Pre-Klenz and sterile water/pad methods. In terms of administrative logistics from a theatre and SSD perspective no adverse issues, such as instrument corrosion, were identified with either of the trialed pre-cleaning solutions.

### **Costings**

Details of background information linked to costings of different components for the pre-cleaning agents is summarized in Supplemental Tables XVI-XVIII. In summary (and assuming products used for the 7,355 neurosurgical trays reprocessed annually at Cowlairs SSD), the equivalent NHS bags could produce a cost saving of 91% (£7,355 versus £440). The trial using sterile water and wound pads produced a 25% saving (£956) per annum. Further cost savings can be made using tap water and tray liner producing an 89% saving (£3,457 pa).

### **Optimising the cleaning process**

Using the in-situ protein assay (ProReveal) the combination of the numbers of cleaned instruments versus the remaining protein per instrument side following cleaning is summarized in Figure 2. These results demonstrated that 163/187 (87%) met a cleanliness threshold criteria [19,20] of  $< 5$  µg protein/instrument side and 179/187 (96%) were less than 10 µg protein/instrument side. Analysis of instrument surface area versus residual protein on cleaned instruments is summarised in Figure 3.

Investigation into patterns of residual protein levels of those instruments that crossed a 20 µg protein instrument threshold could not identify consistent patterns (ineffective washer run, design of instrument or surface area for example) during the wash process that could account for these differences. However, an incidental finding linked to opportunistic sampling of a set of periosteal elevators highlighted a potential confounding factor in the cleaning process (Supplemental figures 3,4). The periosteal elevators, with a flat and easy to clean surface had surprisingly high residual protein levels ranging from 34-451 µg /instrument whilst other instruments from the same set had significantly lower levels. This finding prompted

investigation into the loading patterns of neurosurgical sets, which noted that there was no standard protocol for loading sets of instruments into the washing basket leading to a risk of “shadowing” and subsequent impaired cleaning of instruments (Supplemental figure 1). Misloading of sets into washing baskets was a random process leading to the pattern of residual protein noted on instruments. Reproduction of the detailed loading pattern used during the performance qualification testing where cleaning efficacy was established is essential for each washer run for reproducible cleaning outcomes. It should also be apparent that the test load used during performance qualification should ideally be representative of a neurosurgical set (ref to SHTM 2030 new ref 21). Until issues surrounding the loading patterns of instruments in wash baskets could be resolved further work on use of statistical process control methodology could not be advanced as part of this project.

## Discussion

Previous workers have demonstrated the importance of maintaining surgical instruments in a moist state prior to loading into a washer disinfectant (11,12,20). Replication of this fundamental principle was not the aim of this project, rather we provide quantitative data on cleaning efficacy and equivalence of more cost effective measures for improving cleaning that could be widely adopted and aid in risk reduction from iatrogenic CJD transmission. The use of two different protein detection approaches provides a unique in-sight into the efficacy of the cleaning process at a large SSD.

Previous studies (17,22) have reported residual contaminants on instruments assayed from a variety of SSD's in the UK. This earlier quantitative work on protein residues is a useful benchmark from which to judge the effectiveness of multiple improvement changes in SSD decontamination processes in Scotland (8,9). Findings from these earlier studies indicated protein residues up to 2.2 mg protein instrument (range of medians reported 8-91 µg protein/instrument) and using an energy dispersive x-ray analysis (22) assay 120 surgical instruments from a range of specialties had a range of medians from 267-756 µg protein/instrument set. It is of interest to note that these earlier reports assayed instruments following the steam sterilization process, whether this additional step exposing residual protein to steam at 134°C increases or decreases estimates of residual protein is unknown. Furthermore, no details were presented on the validation of the washers or the wash cycle/detergent combinations to which the instruments were exposed. The work reported here using the SDS elution and OPA quantitation methodology is similar to one of the earlier studies (17) and also using techniques with a higher resolution have confirmed that routinely

reprocessed neurosurgical instruments using the cleaning processes in Cowlairs SSD have significantly lower residues of protein detected. We extend further knowledge by placing these results into the context of the washer cycle used for reprocessing.

Analysis of residual protein levels using ProReveal technology and reference to the recent ACDP recommendations of  $<5 \mu\text{g}$  protein/instrument side (19) demonstrated that 163/187 (87%) met this criteria and 179/187 (96%) were less than  $10 \mu\text{g}$  protein/instrument side. In the context of the ACDP proposal (19) that a "lower level is necessary for neurosurgical instruments" but remains unspecified we show in Figure 2 that 122 instruments (65%) would be  $\leq 2 \mu\text{g}$  of residual protein per instrument side. However, the rationale for a lower limit for neurosurgical instruments (or indeed the  $5 \mu\text{g}$  limit) is unclear. In terms of protein levels/ $\text{cm}^2$  instrument surface all instruments were below the proposed new International standard (23) surgical instrument clean threshold of  $6.4 \mu\text{g}/\text{cm}^2$ . With reference to the SDS elution and OPA analysis results mapped against the RKI (German) (24) standard cleanliness threshold of  $<100 \mu\text{g}/\text{instrument}$  there were 347/351 (99%) cleaned instruments that met this criteria.

A number of previous studies (11,12) and UK (England) guidance (20) have identified the importance of maintaining a moist environment around used surgical instruments prior to cleaning. This has led to the marketing of a wide variety of pre-cleaning "wetting" agents designed with this objective in mind. There have been anecdotal reports of problems caused by some of these agents such as, excessive foaming during the wash stage leading to washer pump problems and residues remaining after drying out of the wetting agent. In addition, with a typical SSD using several thousands of tray sets per year there is a significant cost implication. The cost of the preferred NHS method (using "NHS" plastic bags plus wound pad plus sterile water) produced significant cost savings that could be further improved by the use of tap water and tray liners. An interesting confounding variable came to light during the course of the study whereby three instruments (periosteal elevators) with simple, flat and smooth surfaces recorded high protein levels post cleaning that could not be explained by their simple easy to clean construction. We suspect that these devices had been incorrectly loaded into the washer baskets, further confounding efforts to rationalise cleaning improvements for neurosurgical instruments.

In conclusion, we present quantitative data on residual protein levels on neurosurgical instruments post washing to provide an in-sight into compliance with recent guidance on thresholds designed to reduce the risks for iatrogenic disease transmission linked to vCJD. We demonstrate that 163/187 (87%) of neurosurgical instruments were  $<5 \mu\text{g}$

protein/instrument side. Loading patterns of instruments into the washer disinfectant is a critical control point which should be optimised and reproduced at subsequent loadings prior to wide spread introduction of quantitative residue technologies on cleaned instruments. We also demonstrate that relatively simple and inexpensive measures can lead to significant improvements in the cleaning of neurosurgical instruments.

### **Role of the funding source**

This study was funded by a grant (ref SIRN 008) from the Scottish Infection Research Network. The funders had no role in the collection, analysis, conclusions of this study or the preparation of this manuscript.

### **Acknowledgements**

We wish to acknowledge the work of Dr Tim Tomkinson for preliminary investigations on this project and Dr Meg Pajak for reporting the surface area of neurosurgical instruments.

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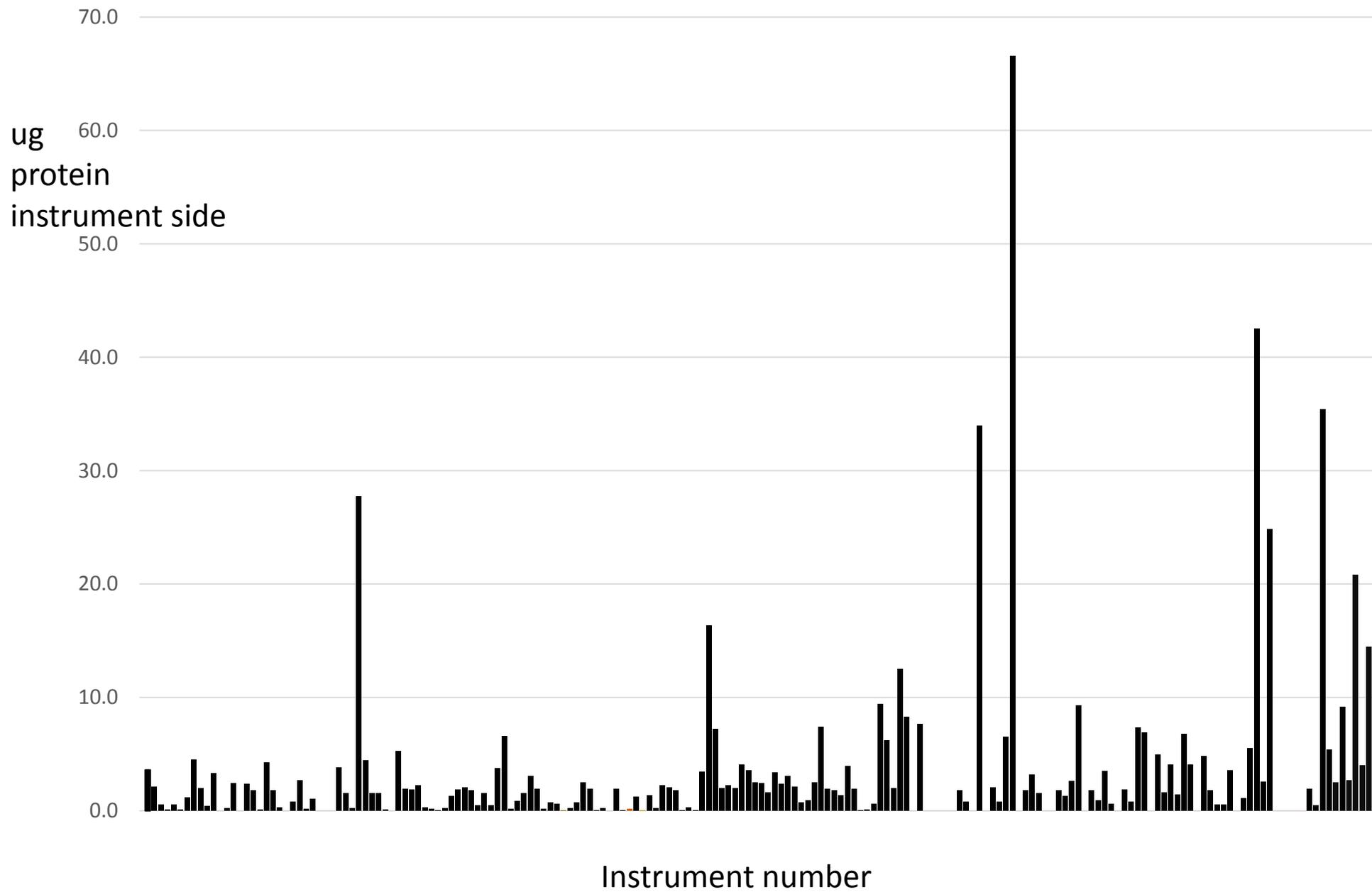
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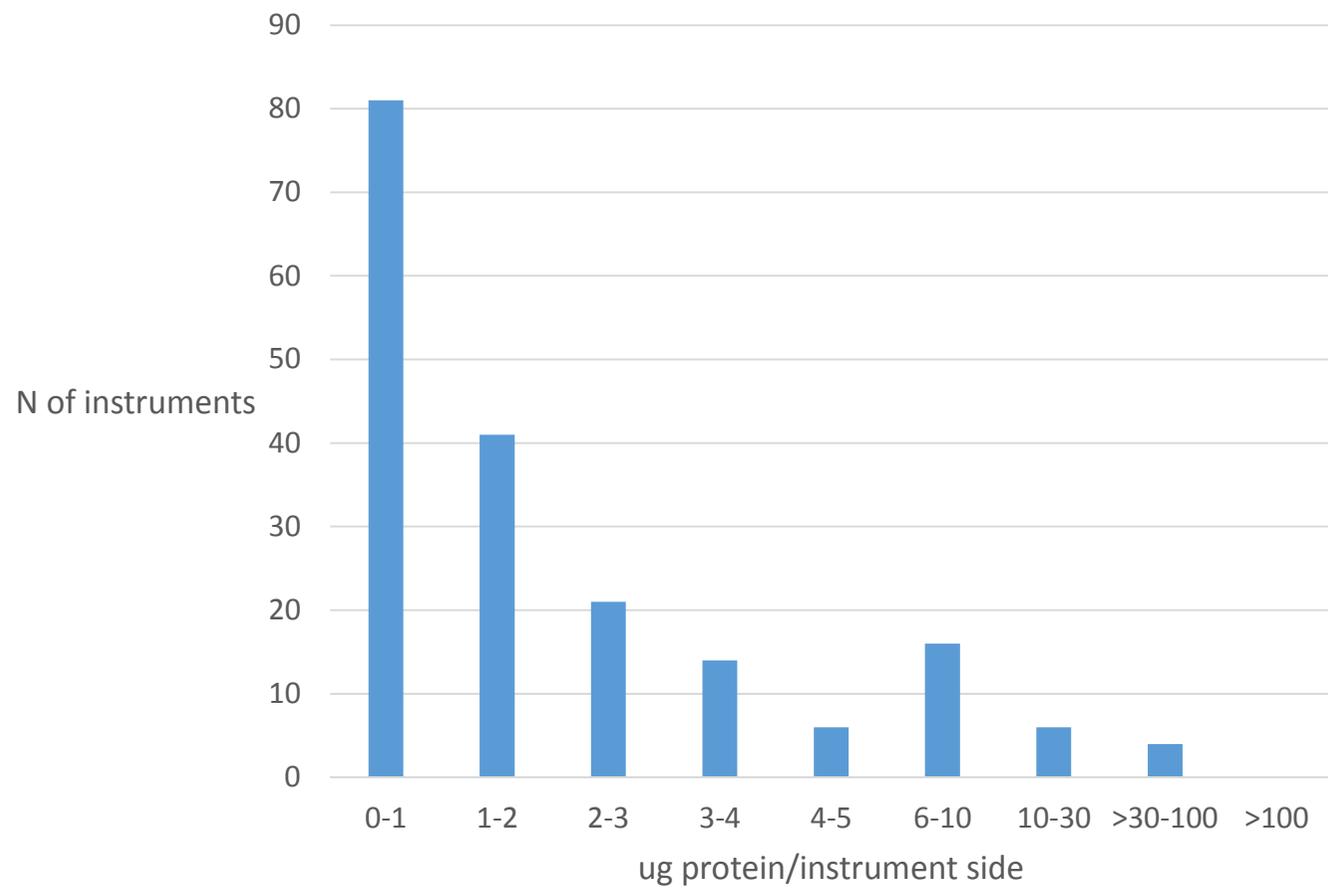
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**Table 1 Residual protein levels of soiled discs with or without a range of pre-cleaning agents and followed by 5 minutes wash (ProReveal analysis)**

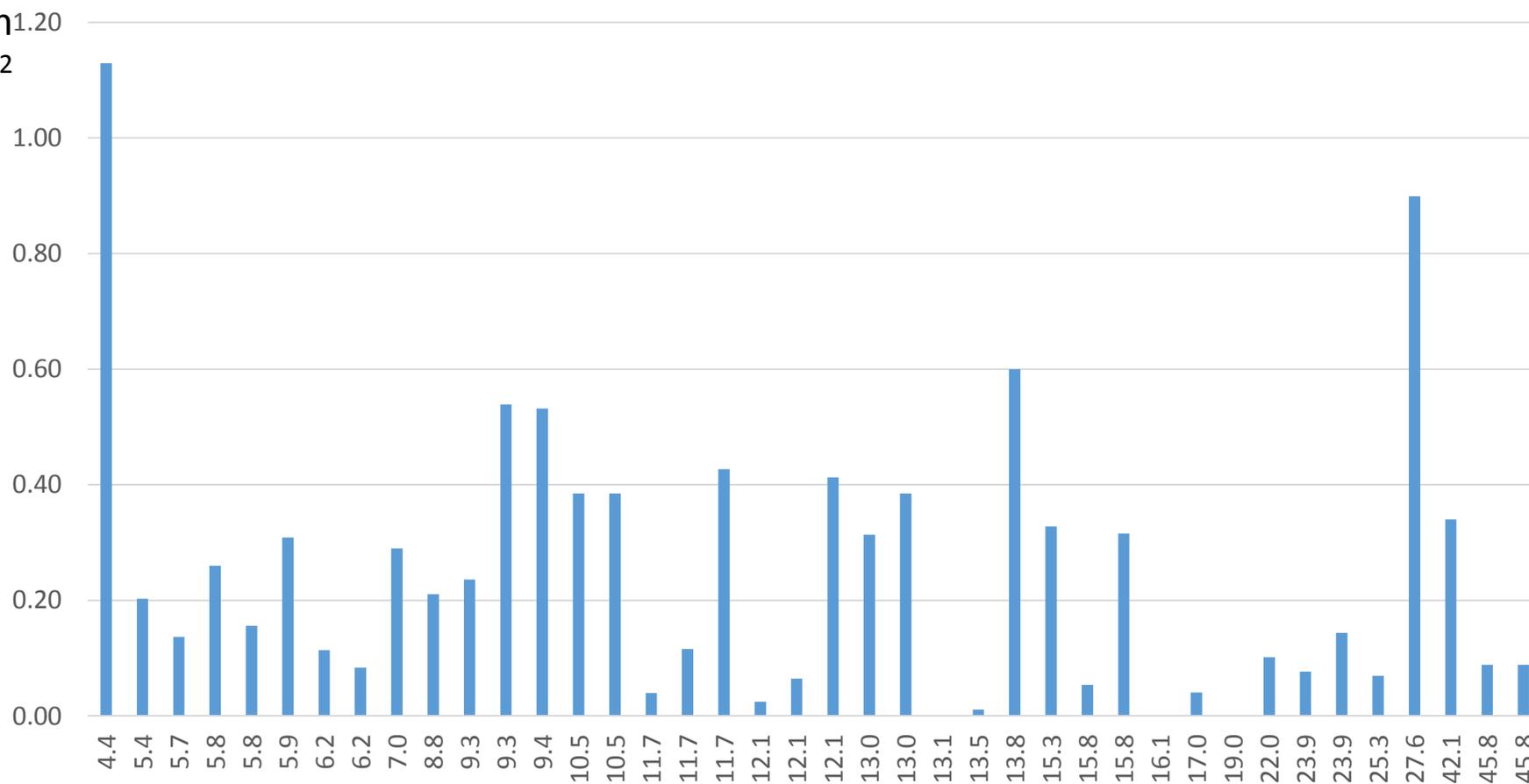
	No bag/no wetting agent	Bag/no wetting agent	Bag/H <sub>2</sub> O as wetting agent	Bag/Steris Pre-Klenz	Bag/Ebiox Neozyme	Bag/Ruhof Prep-zyne	Bag/Ruhof Forever wet
Mean (ug protein /disc)	171	49	21	21	48	33	40
Median (ug protein /disc)	122	52	15*	7*	14	31	39
SD	114	27	11	24	61	11	22
Range (ug protein /disc)	51-379	15-89	11-43	3-68	4-172	11-49	14-76

(\*P<0.001 compared to no bag and no pre-cleaning agent)

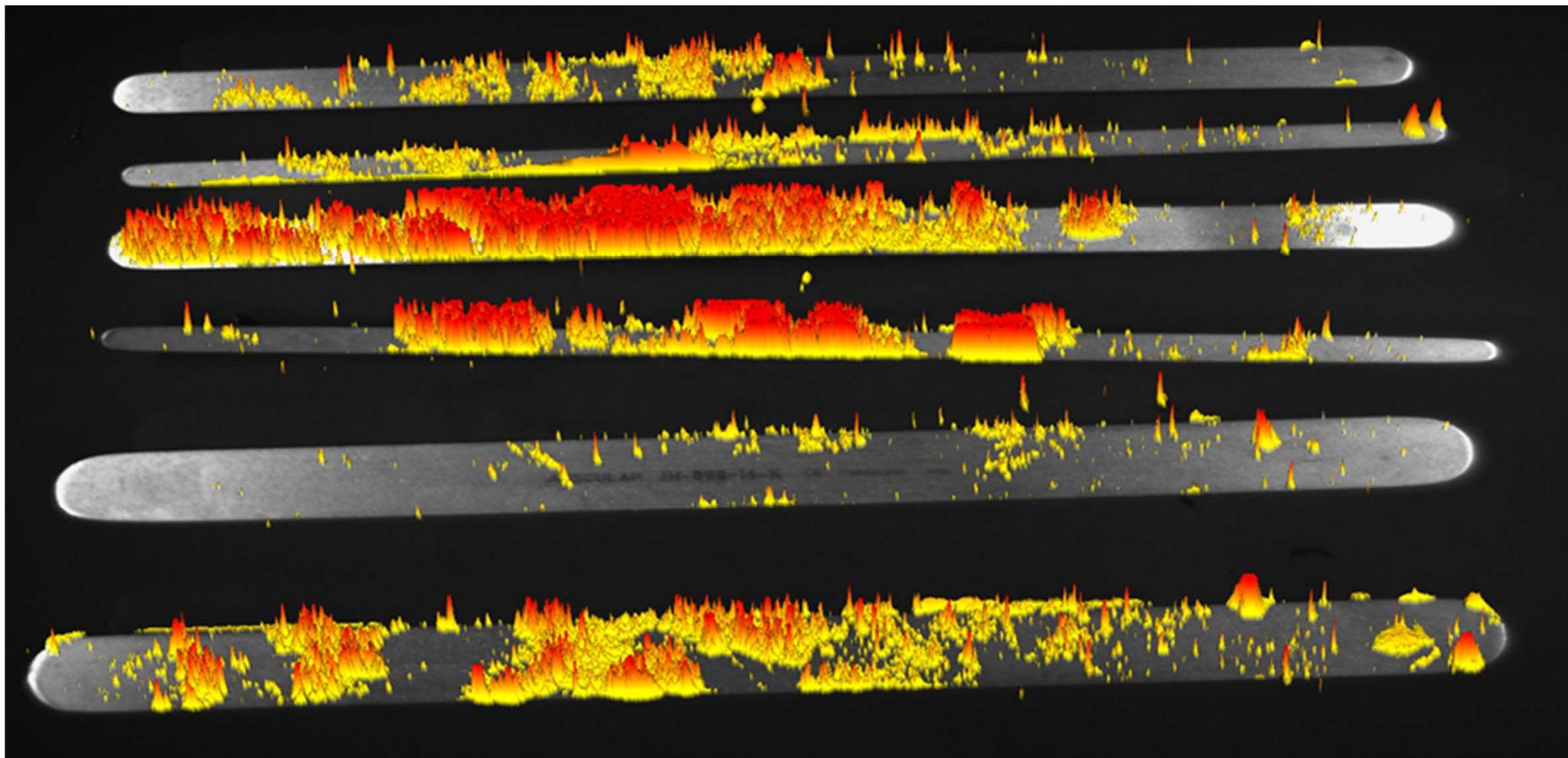




Median  
protein  
ug/cm<sup>2</sup>



Median instrument surface area/cm<sup>2</sup>



## Log scale ug protein instrument side

