ENDOSCOPE REPROCESSING WITH BRUSHLESS CLEANING PROCESS CONDITIONS

Lionel PINEAU PhD

BIOTECH-GERMANDE

HYGIÈNE - FORMATION - ÉVALUATION - RECHERCHE & DÉVELOPPEMENT

CONTENT

- General considerations
  - Endoscope reprocessing, channel brushing, cleaning claims…
- Description of the 2013 study (with brushing)
  - Design and objectives,
  - Method, results and discussion.
- New data collected in 2014 (without brushing)
  - Design and objectives,
  - Results.

ENDOSCOPE REPROCESSING

General Considerations

ESGE±ESGENA guideline: Cleaning and disinfection in gastrointestinal endoscopy Update 2008

MANUAL BRUSHING
General Considerations

Manual brushing of scope channels is often recommended by guidelines (eg, ESGENA, BSG)[1,2] but:

- A growing number of experts believe that this stage might not be required if scopes are reprocessed using appropriately validated Endoscope Cleaning and Reprocessing technology[3],
- According to French guidelines, this requirement might be reviewed in case of appropriate technological evolution[4].

ESGENA = The European Society of Gastroenterology and Endoscopy Nurses and Associates; BSG, British Society of Gastroenterology.

1. Beilenhoff U, et al. *Endoscopy*. 2008;40(11):939-957.
2. British Society of Gastroenterology. http://www.bsg.org.uk/images/stories/docs/clinical/guidelines/endoscopy/decontamination_2008.pdf. Accessed October 15, 2014.
3. Alfa MJ, et al. *BMC Infect Dis*. 2010;10:200-213.
4. Guide for the Use of Washer-Disinfectors for Endoscopes. November 2003. Available at: http://www.sante.gouv.fr/guide-de-bonnes-pratiques-de-desinfection-actualisation.html. Accessed October 15, 2014.

CLEANING CLAIMS*

US and Australian Positions

- Some AERs have already received clearance from the US FDA[1] or the Australian TGA[2] for "cleaning claims".
- Benchmarks proposed by AAMI[3]—based on the study by M. Alfa[4]—for adequate cleaning are <6.4 µg/cm^2 for residual proteins and <4 $\log_{10}$ viable bacteria/cm^2.

AER = automated endoscope reprocessor; FDA = Food and Drug Administration; TGA = Therapeutic Goods Administration; AAMI = Association for the Advancement of Medical Instrumentation.

*No manual brushing prior to automatic reprocessing.

1. US Food and Drug Administration. Medical Devices. Available at : http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm194429.htm. Accessed October 15, 2014.
2. Infection Prevention and Control Manual. Available at: http://www.health.vic.gov.au/infectionprevention/downloads/inf-con-9.pdf. Accessed October 15, 2014.
3. AAMI. Sterile Processing Benchmarks. Available at: http://www.aami.org/spb/index.html. Accessed October 15, 2014.
4. Alfa MJ, et al. *Am J Infect Control*. 1999;27(5):392-401.

CLEANING CLAIMS

M. Alfa Study

Table 4. Soil in patient-used endoscopes after cleaning but before HLD (worst-case soil after cleaning); soil levels detected per suction channel surface area of device*

Endoscope	Hemoglobin µg/cm²	Bilirubin nmol/cm²	Protein µg/cm²	Sodium ion µmol/cm²	Endotoxin EU/cm²	Carbohydrate µg/cm²	Viable bacteria $\log_{10}$ CFU/cm²
Bronchoscope							
Average	2.19	<LD	6.12	0.94	4.55	<LD	2.89
Median	2.19		6.36	0.77	2.23		2.79
Range	0-4.4		3.51-8.55	0.77-1.54	0.27-19.61		2.17-4.05
Duodenoscope							
Average	<LD	<LD	1.17	0.08	0.02	1.79	2.22
Median			1.20	0.07	0.002	1.18	1.94
Range			0.20-2.26	0.07-0.13	0.001-0.06	0-5.28	1.49-3.17
Colonoscope							
Average	<LD	<LD	0.87	0.05	0.07	<LD	1.82
Median			0.96	0.05	0.03		1.82
Range			0.52-1.19	0.05-0.052	0.005-0.46		0.89-2.33

*Average and median soil amount per square centimeter for 10 of each type of endoscope (range of soil concentrations). The inner suction channel dimensions for all endoscopes used is given in Table 1 (surface area calculated as length × circumference of inner suction channel).

HLD = high-level disinfection; EU = endotoxin units; CFU = colony-forming units; LD = limit of detection.

Alfa MJ, et al. *Am J Infect Control*. 1999;27(5):392-401.

CLEANING CLAIMS

EN and ISO Positions

- ISO TC 198 WG13, in charge of revising the EN ISO 15883-5, has been working for several years on the definition of an acceptable cleanliness level for endoscopes after reprocessing in an AER.
- Several values have been proposed, from 2.5 µg/cm² to 20 µg/cm² residual protein.

EN = English; ISO = International Organization for Standardization; TC = Technical Committee; WG = Working Group; AER = automated endoscope reprocessor.

EN-ISO 158883 Guideline. Available at: http://www.wfhss.com/html/educ/recommendations/central-service-recommendation-200705_en.pdf. Accessed 10/11/12.

CLEANING CLAIMS (*cont*)

Latest EN and ISO Positions [1]

- 4.8.2 The acceptable limit of detection of protein on a cleaned device shall be < 6.4 µg/cm^2.
- 4.8.3 Other soil indicators and their acceptable limits of detection, if used on a cleaned device, include:

  a) TOC, < 12 µg/cm^2;

  b) Carbohydrate, < 1.8 µg/cm^2;

  c) Hemoglobin, < 2.2 µg/cm^2;

  d) Endotoxin, < 2.2 EU/cm^2;

(1) Draft ISO/WD TR15883-5 for comment. Date of document: 2014-07-07

(2) Michelle J. Alfa , Iram Fatima MSc , Nancy Olson. Validation of adenosine triphosphate to audit manual cleaning of flexible endoscope channels. Am J Infect Control 2012 (2012) 1-4

CLEANING CLAIMS (*cont*)

EN and ISO Positions

Experts agree that preliminary tests need to be performed to gain a better idea of:

- The amount of organic material present on patient-used flexible endoscopes before reprocessing,
- The amount of soil remaining on the endoscope after manual brushing,
- Whether the same level of efficacy can be reached with a fully automated process.

EN = English; ISO = International Organization for Standardization.

EN-ISO 158883 Guideline. Available at: http://www.wfhss.com/html/educ/recommendations/central-service-recommendation-200705_en.pdf. Accessed 10/11/12.

Evaluation of endoscope cleanliness after reprocessing: a clinical-use study

L. Pineau, E. De Philippe[1]*

The need for manual brushing of endoscope channels before cleaning and disinfecting them in automatic endoscope reprocessors (AERs) is more than ever debated. Most European national guidelines recommend or require manual brushing, while the U.S. Food and Drug Administration (FDA) and the Australian Therapeutic Goods Administration have already accepted claims of high-level disinfection by some AERs without the need for manual brushing when bedside pretreatment is performed.

This study quantitatively assayed total protein, total organic carbon, and viable aerobic bacteria remaining in endoscopes by the FDA for an automatic cleaning claim (i. e., < 6.4 µg/cm² for residual protein and < 4 $\log_{10}$ viable bacteria/cm²) in 91 % and 99 % of cases, respectively. From the 31 endoscopes that were completely reprocessed before sampling, all bacterial counts reached the limits established for automatic cleaning claims. Mean total organic carbon after the complete cycle was one-third the value after the automatic cleaning stage (0.9 µg/cm² after cleaning and disinfection vs. 2.8 µg/cm² after only cleaning; not statistically significant). After full processing 23 % of total organic carbon values were lower than the detection limit of the method, in contrast to 67 % for to-

KEY WORDS
- endoscope
- disinfection
- contamination
- reprocessing
- manual cleaning

doscopes are reprocessed in an appropriately validated automatic endoscope reprocessor (AER).

Some AERs have already received U.S. Food and Drug Administration (FDA) or Australian Therapeutic Goods Administration clearance for cleaning claims that

DESIGN AND OBJECTIVES

Study to evaluate the performance of manual brushing and AERs against the following benchmarks:

- <6.4 µg/cm^2 for residual proteins,
- <4 $\log_{10}$ viable bacteria/cm^2,
- <12 µg/cm^2 for TOC.

Each step of the reprocessing procedure was performed according to recommendations and involving AERs:

- Quantitative assay for residual proteins and viable bacteria performed after each of 4 steps.

AER = automated endoscope reprocessor.

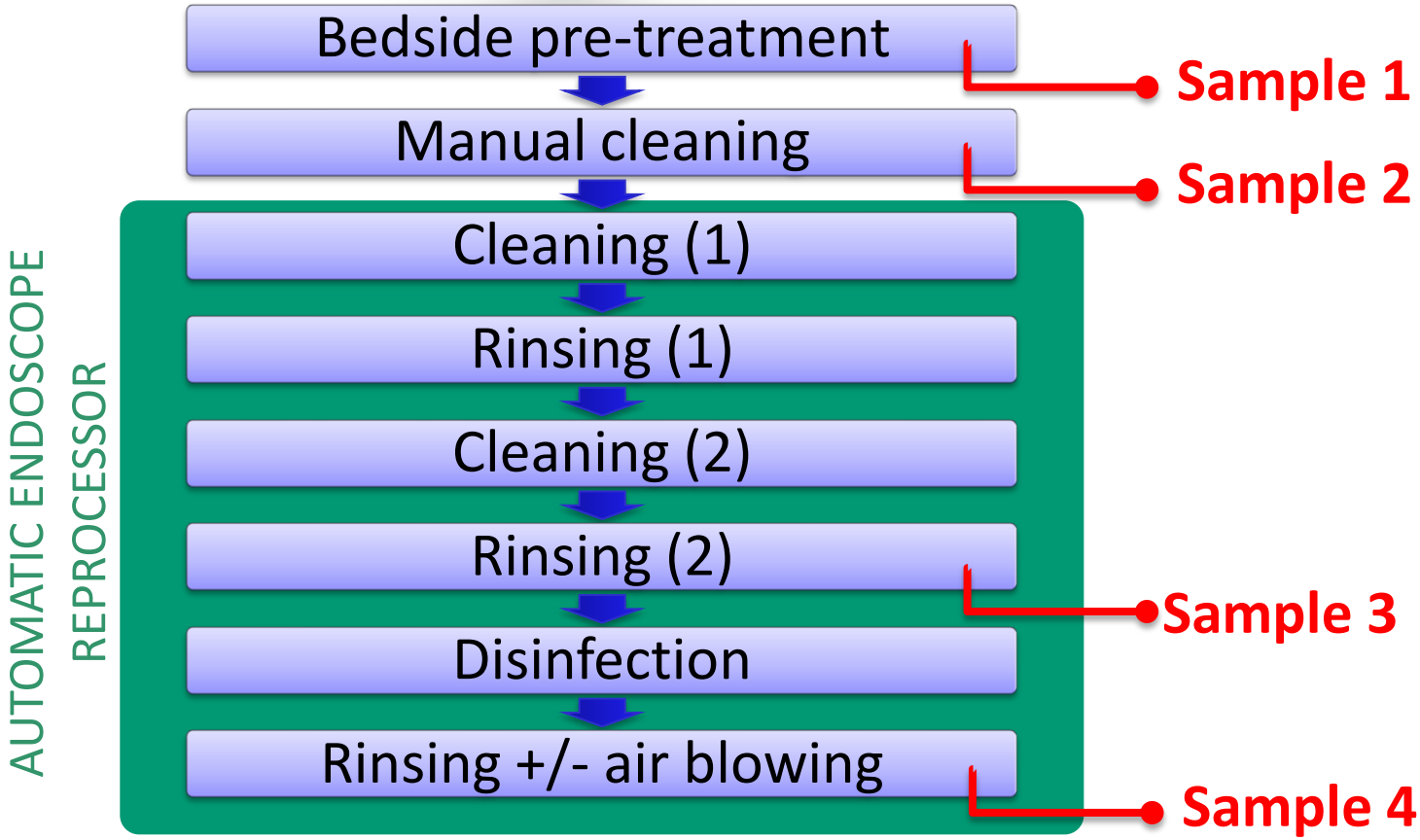
METHOD

General

- 9-months study (07/2011 to 04/2012),
- 1 public and 3 private hospitals in France,
- 206 endoscope samples:
  - 87colonoscopes,
  - 93 gastroscopes and duodenoscopes,
  - 26 bronchoscopes
- Instrument brand:
  - 65% Olympus,
  - 33% Fujinon,
  - 2% not specified

METHOD

Standard Reprocessing Procedure



METHOD

"Flush-Brush-Flush" (Alfa 2006)[1]

- All channels were flushed with 10 mL of WFI (water for injection),
- Suction and biopsy channels were brushed 3x with a sterile brush,
- All channels were flushed with 10 mL of WFI + 2 x 50 mL of air,

60 mL of WFI + brush

Alfa MJ, et al. *Am J Infect Control*. 2006;34(9):561-570.

METHOD

Sample Analysis

9 mL

9 mL neutralizing solution 2
2 x C

0.2 µm membrane filtration
incubation 5 days at 30°C on
PCA agar

Total viable count
(CFU/endoscope)

50 mL

Aurora TOC Analyzer
(OI Analytical, model 1030)

Total Organic Carbon
(µg/cm^2 of channel)

1 mL

Protein measurement
Micro BCA™

Proteins
(µg/cm^2 of channel)

PCA = plate count agar; TOC = total organic carbon; CFU = colony-forming units.

METHOD

Recovery Ratio

The recovery ratio of the sampling method was determined by repeated rounds of sample collection according to ISO 11737-1 annex C1.

Endoscopes	Mean Recovery Ratio		
	Total Organic Carbon	Proteins	Bioburden
Bronchoscopes	0.90	0.83	0.88
Gastroscopes	0.35	0.44	0.98
Colonoscopes	0.47	0.76	1.00

ISO = International Organization for Standardization.

ISO 11737-1 annex C1 Guideline. Available at: http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=46116. Accessed 10/15/12.

RESULTS

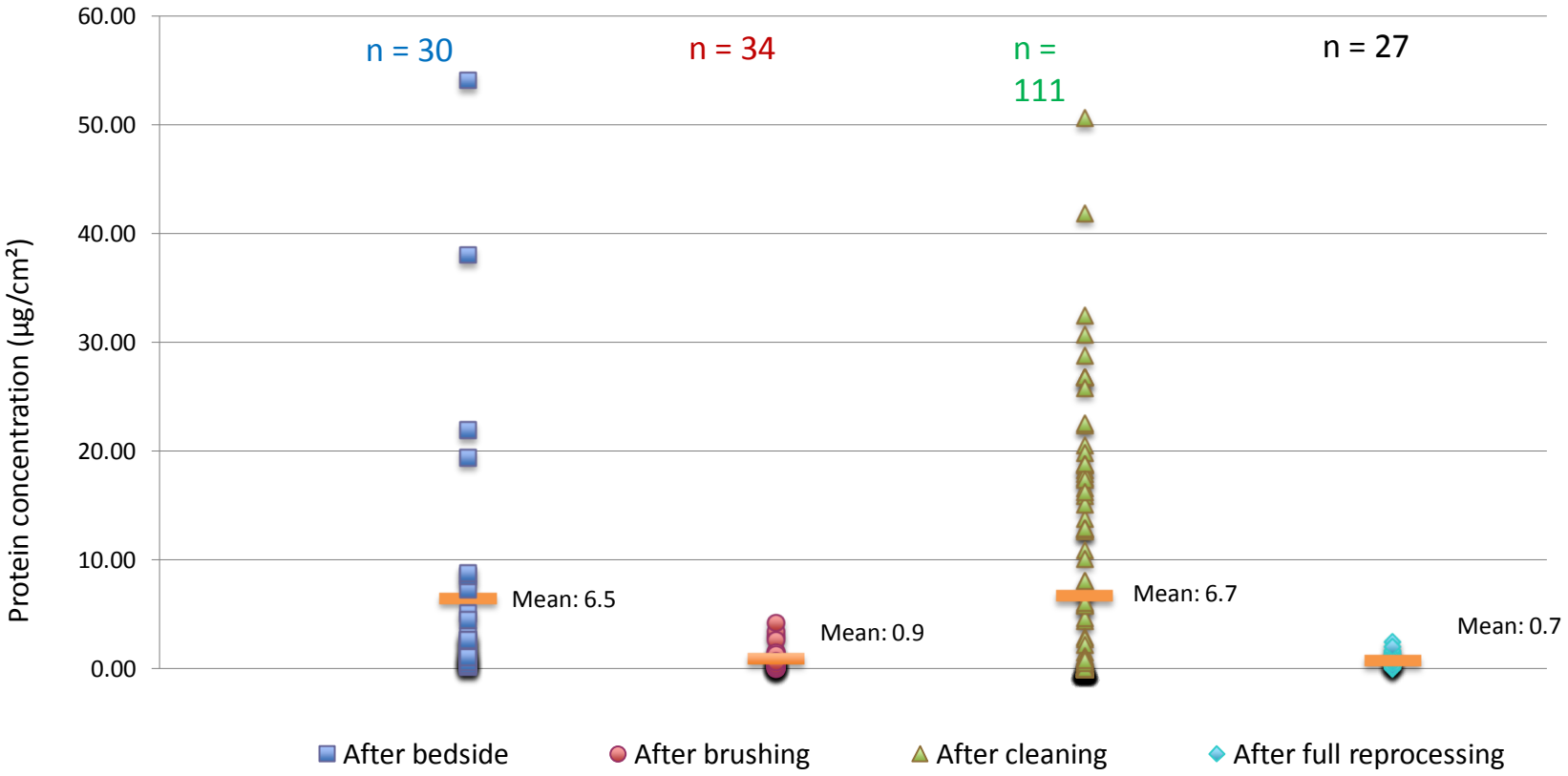
Bioburden

- Wide dispersion of values after bedside brushing and cleaning in the AER,
- Brushing endoscope channels reduced the bioburden by at least 2 $\log_{10}$,
- After cleaning 99% of values were below 4 $\log_{10}$ viable bacteria/cm².

CFU = colony-forming units; DL = detection limit; AER = automated endoscope reprocessor.

RESULTS

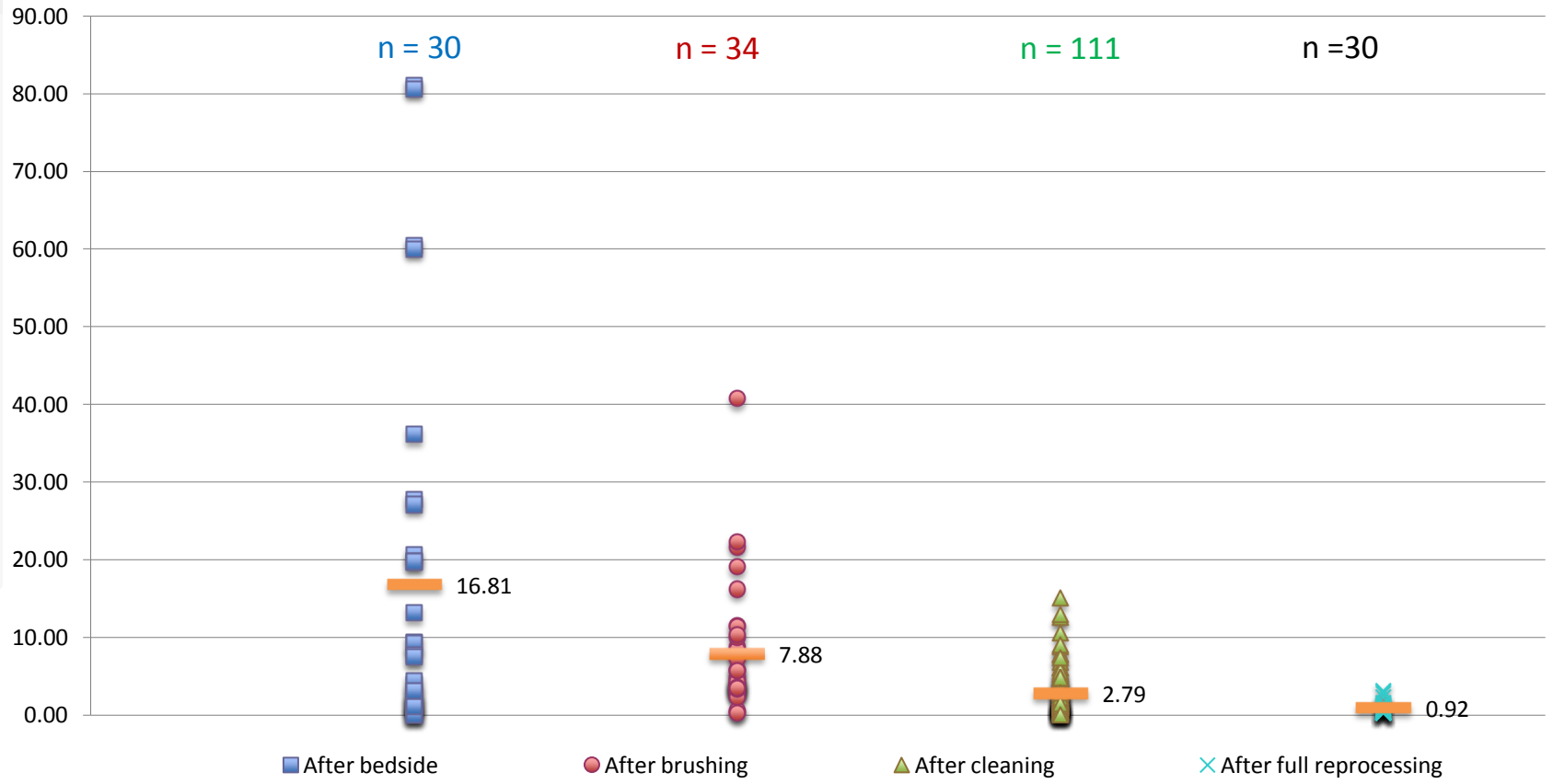
Proteins / Micro BCA™



- Wide dispersion of values after bedside,
- After cleaning 67% of the results were below 6.4 µg/cm^{2,}
- Interference of the detergent used in one AER with the Micro BCA™ method,
- After full reprocessing, 83% of values were lower than the DL.

RESULTS

Total Organic Carbon



- Important dispersion of values after bedside pre-cleaning,
- After cleaning 97% of the results are below 12 µg/cm^2 (91% are below 6.4 µg/cm^2),
- After full reprocessing, 42% of values were lower than the DL.

CONCLUSION OF THE INITIAL STUDY

- Total organic carbon is a more sensitive and reliable measure of residual protein compared to Micro BCA™ (no interference with detergent, lower DL),
- After manual brushing and cleaning in an AER, 91% of TOC values and 99% of measurements of bioburden were consistent with FDA and TGA limits (i.e., <6.4 µg/cm^2 for residual protein and <4 $\log_{10}$ viable bacteria/cm^2),
- Differences in cleaning results are observed between hospitals (eg, manual pre-cleaning, AER, chemicals).

DL = detection limit; AER = automated endoscope reprocessor; TOC = total organic carbon; FDA = Food and Drug Administration; TGA = Therapeutic Goods Administration.

Evaluation of endoscope cleanliness after reprocessing: a clinical-use study

L. Pineau, E. De Philippe¹*

Without brushing

The need for manual brushing of endoscope channels before cleaning and disinfecting them in automatic endoscope reprocessors (AERs) is more than ever debated. Most European national guidelines recommend or require manual brushing, while the U.S. Food and Drug Administration (FDA) and the Australian Therapeutic Goods Administration have already accepted claims of high-level disinfection by some AERs without the need for manual brushing when bedside pretreatment is performed.

This study quantitatively assayed total protein, total organic carbon, and viable aerobic bacteria remaining in endoscopes

by the FDA for an automatic cleaning claim (i. e., < 6.4 µg/cm² for residual protein and < 4 $\log_{10}$ viable bacteria/cm²) in 91 % and 99 % of cases, respectively. From the 31 endoscopes that were completely reprocessed before sampling, all bacterial counts reached the limits established for automatic cleaning claims. Mean total organic carbon after the complete cycle was one-third the value after the automatic cleaning stage (0.9 µg/cm² after cleaning and disinfection vs. 2.8 µg/cm² after only cleaning; not statistically significant). After full processing 23 % of total organic carbon values were lower than the detection limit of the method, in contrast to 67 % for to-

KEY WORDS
- endoscope
- disinfection
- contamination
- reprocessing
- manual cleaning

doscopes are reprocessed in an appropriately validated automatic endoscope reprocessor (AER).

Some AERs have already received U.S. Food and Drug Administration (FDA) or Australian Therapeutic Goods Administration clearance for cleaning claims that

DESIGN AND OBJECTIVES

Study to evaluate in real use situation, the performance of common AERs (without manual brushing) against the following benchmarks:

- <6.4 µg/cm^2 for residual proteins,
- <4 $\log_{10}$ viable bacteria/cm^2,
- < 12 µg/cm^2 for Total Organic Carbon.

Compare the results with the previous study.

AER = automated endoscope reprocessor.

METHOD

Standard Reprocessing Procedure

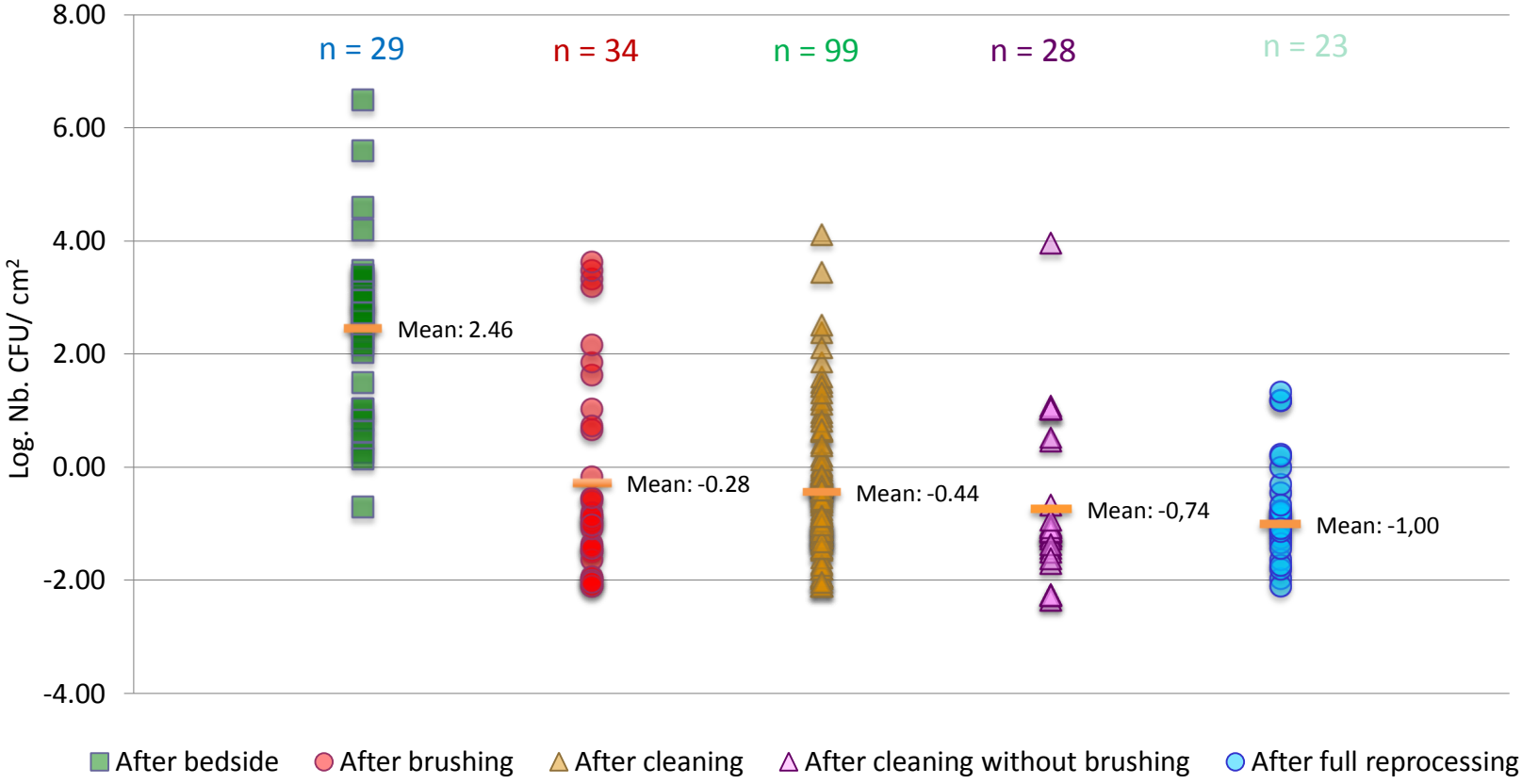
METHOD

General

- 3-months study (2014),
- 1 public and 3 private hospitals in France,
- 53 endoscope samples:
  - 22 colonoscopes,
  - 22 gastroscopes and duodenoscopes,
  - 9 bronchoscopes.
- Instrument brand:
  - 62% Olympus,
  - 24% Fujinon,
  - 14% Pentax.

RESULTS

Bioburden



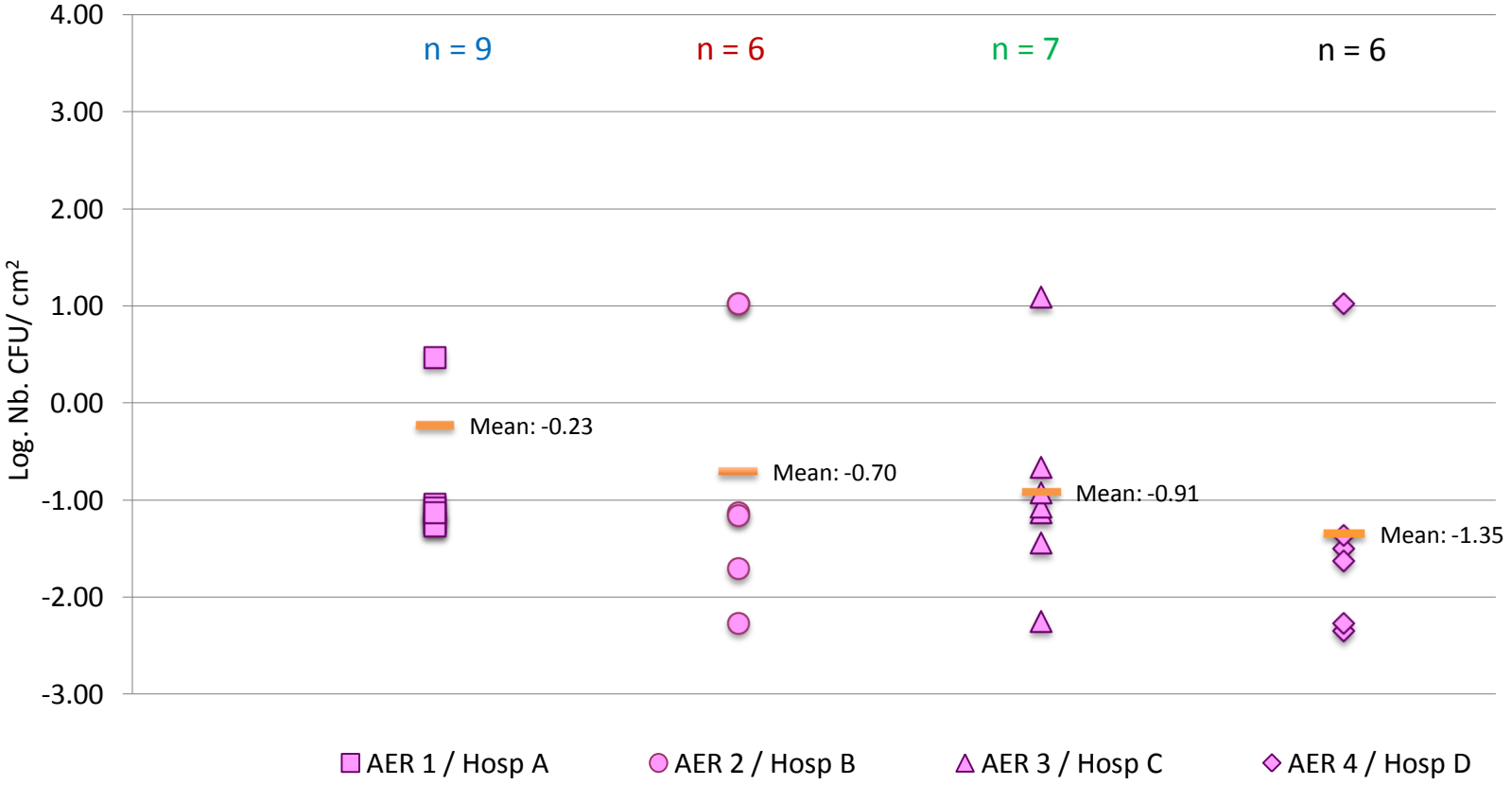
- Endoscope contamination levels after cleaning in the AER are comparable with or without brushing (0.3 $\log_{10}$ difference),
- Brushing endoscope channels reduced the bioburden by at least 2 $\log_{10}$,
- Cleaning endoscope channels in the AER without brushing reduced the bioburden by at least 2 $\log_{10}$.

CFU = colony-forming units; DL = detection limit; AER = automated endoscope reprocessor.

RESULTS

Bioburden

After cleaning without brushing

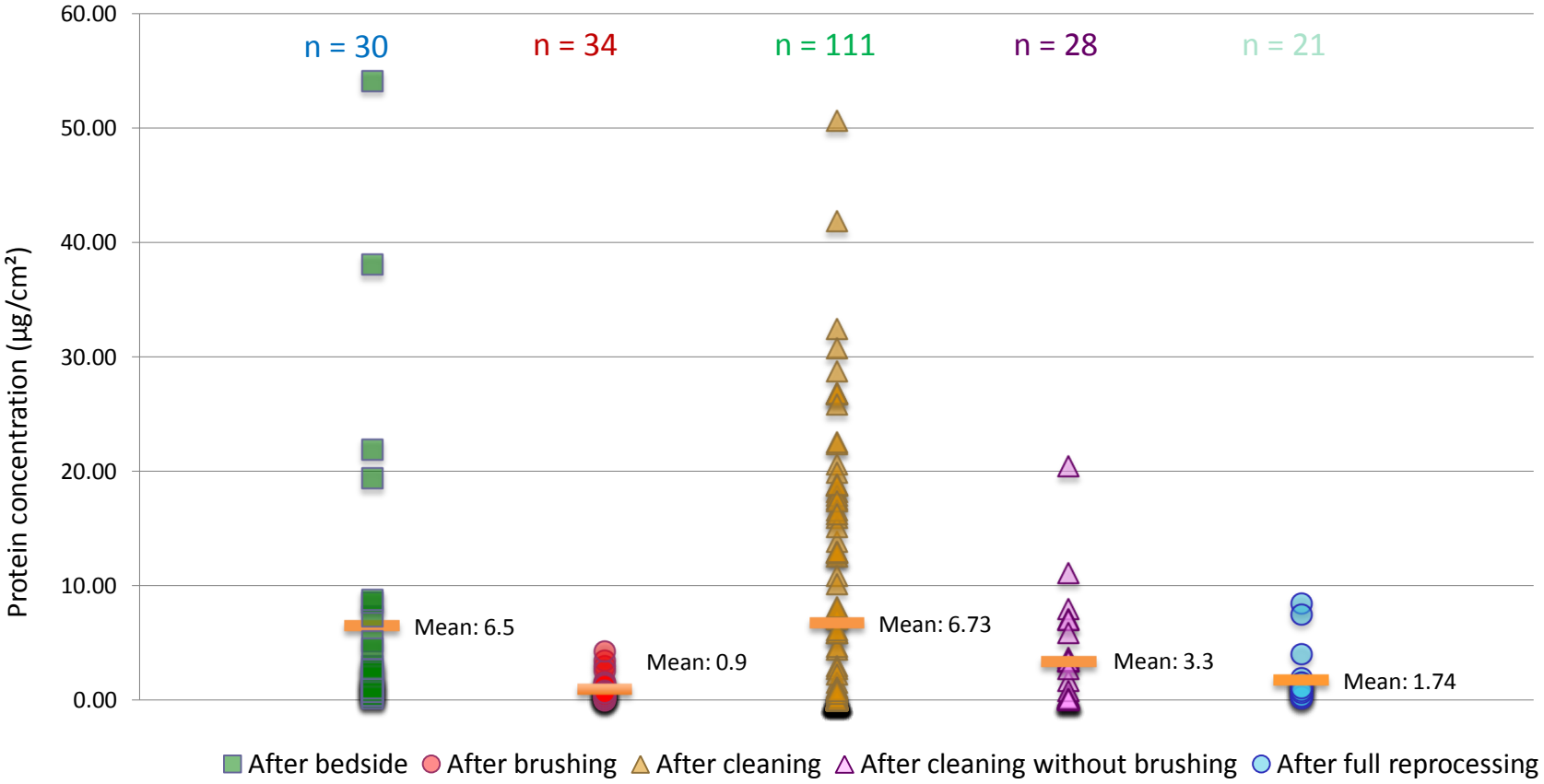


- Results are comparable between AER/hospitals,
- After cleaning without brushing 100% of values are below 4 $\log_{10}$ viable bacteria/cm^2.

CFU = colony-forming units; DL = detection limit; AER = automated endoscope reprocessor.

RESULTS

Proteins / Micro BCA™

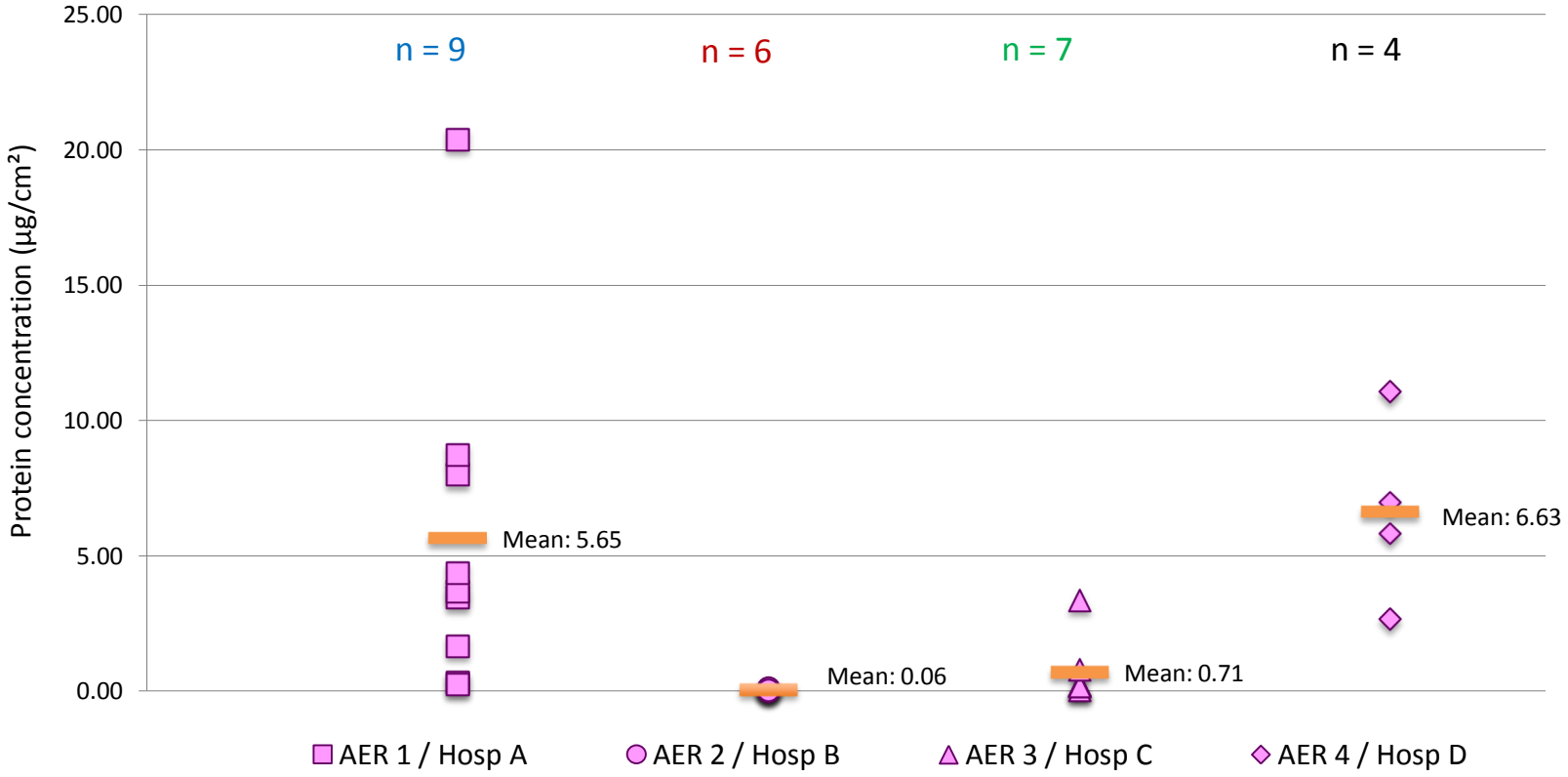


- After cleaning with brushing 67% of the results were below 6.4 µg/cm²,
- After cleaning without brushing 79% of the results were below 6.4 µg/cm²,
- Interference of the detergent used in one AER with the Micro BCA™ method.

RESULTS

Proteins / Micro BCA™

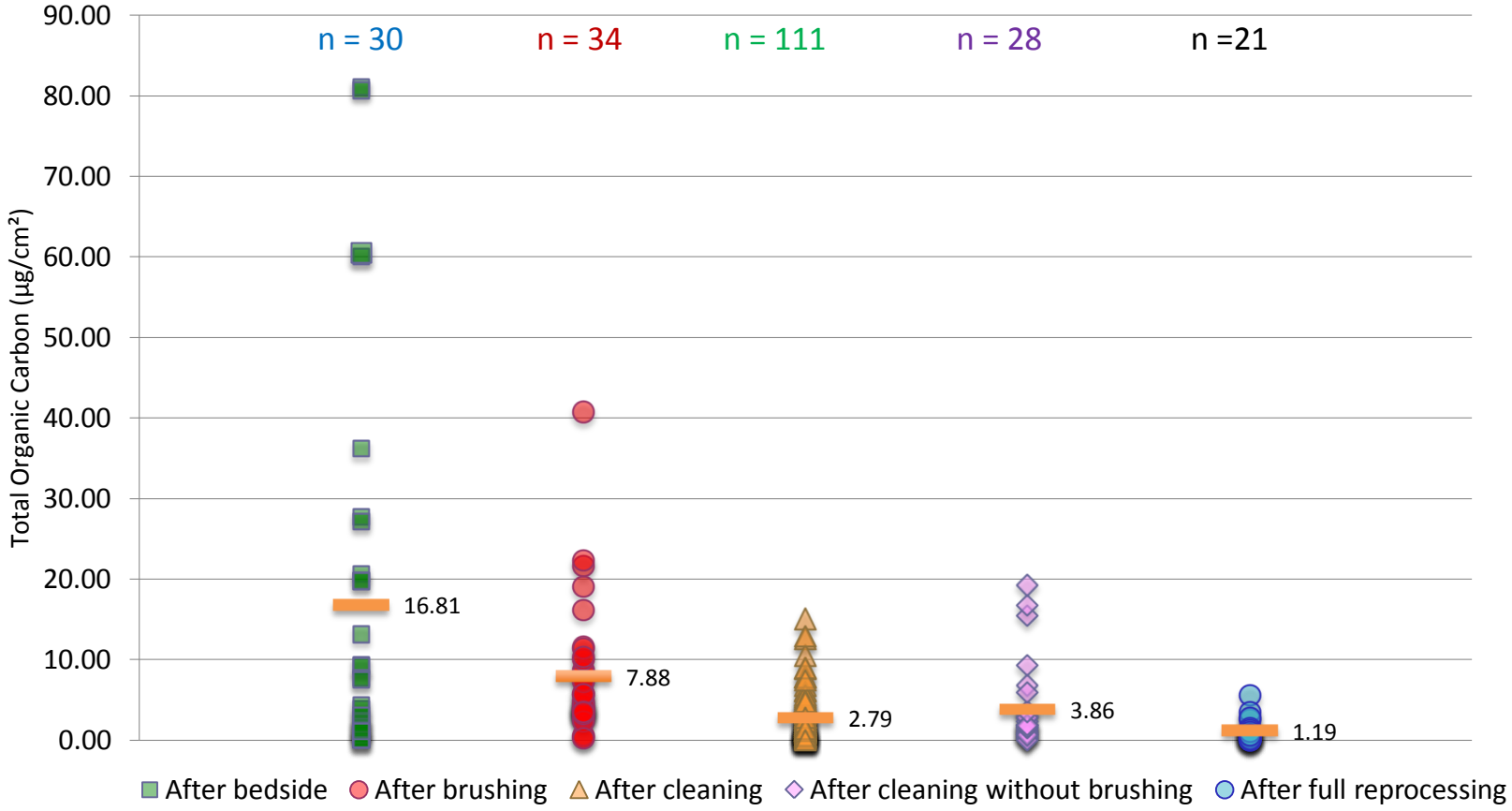
After cleaning without brushing



- Some differences are observed between AER,
- Interference of the detergent used in AER 1 and 4 with the Micro BCA™ method,
- For AER 2 and AER 3, after cleaning without brushing, 100% of the values are lower than 6.4 µg/cm² (92 % of the values are lower than 0.8 µg/cm²).

RESULTS

Total Organic Carbon



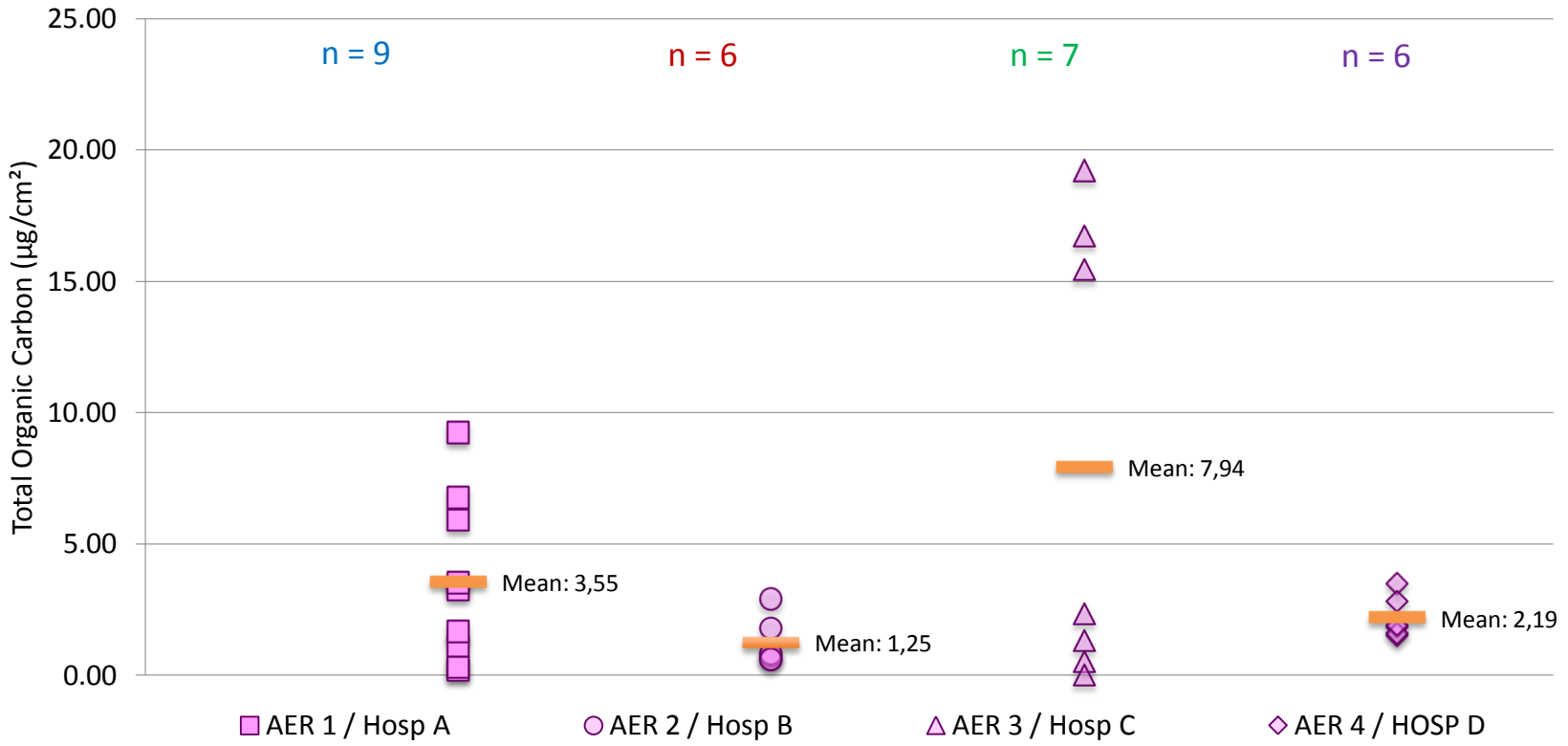
- The mean TOC concentration is slightly higher when brushing is not performed,
- After cleaning with brushing 96% of the results were below 10 µg/cm^2,
- After cleaning without brushing 89% of the results were below 10 µg/cm^2.

BIOTECH-GERMANDE

RESULTS

Total Organic Carbon

After cleaning without brushing



- Important dispersion of values are observed for AER 3 (43% of the values are higher than 12 µg/cm²),
- After cleaning without brushing in AER 1, AER2 or AER 4, 95% of the results are below 6.4 µg/cm² and 100% below 12 µg/cm².

DISCUSSION

- For the 4 AERs, suppression of channel brushing does not induce any increase in the number of viable bacteria found in endoscope channels after cleaning in the AER.
- For AER 1, 2 and 4, proteins and/or TOC measurements demonstrate that the same level of efficacy can be reached with or without brushing with 100% of the values consistent with the proposed benchmarks (i.e., <6.4 µg/cm^2 for residual protein, <4 $\log_{10}$ viable bacteria/cm^2, <12 µg/cm^2 for TOC).
- For AER 3, the TOC results confirm that for some endoscopes brushing is still required to compensate the lower efficacy of the AER.

DL = detection limit; AER = automated endoscope reprocessor; TOC = total organic carbon; FDA = Food and Drug Administration; TGA = Therapeutic Goods Administration.

CONCLUSIONS

- Withdrawal of a manual brushing requirement will be most likely the next big breakthrough in the field of endoscope cleaning and disinfecting.

- Nevertheless, this will be possible only provided that the monitoring technology of AERs and the validations performed (type tests and performance qualification) guarantee that the minimum effective process fluids conditions are achieved through each channel of all endoscopes intended to be reprocessed in the AER.

- Pre-cleaning (i.e. bedside pre-treatment) will always be performed.

AER = automated endoscope reprocessor.

THANK YOU VERY MUCH…

BIOTECH-GERMANDE

HYGIÈNE - FORMATION - ÉVALUATION - RECHERCHE & DÉVELOPPEMENT