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Storage environment of surgical instruments before reprocessing

*Part of the **RSME** Research Program*

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Background

- Reprocessing of surgical instruments must commence as soon as possible post-surgery
- Transport and storage occur in a humid environment until reprocessing is commenced
(Instrument Preparation Working Group 2018, NIR 2019)

Why

- The primary concern is the risk of corrosion and thereby destruction of the instrument
- Drying times beyond 15 minutes reduces the effect of subsequent cleaning
(Lipscomb et al. 2007, Secker et al. 2011, Secker et al. 2015)



Aim

To test if a humid environment for storing surgical instruments until reprocessing reduces the occurrence of corrosion, as well as the occurrence and accumulation of biological material compared to instruments stored in a dry environment

HYPOTHESIS

Methods

Instruments:

- Forceps and irrigation syringes

Contamination:

- Human EDTA blood amended with *Enterococcus faecalis* ATCC 29212 (final concentration: $1.5 \cdot 10^8$ CFU/mL)

Washing, disinfection and sterilization:

- The washer-disinfector and autoclave using standard protocols for the CDS at Aalborg University Hospital, Denmark



Protein residue

- 108 forceps & 108 syringes
- Contaminated before each reprocessing cycle
- Stored for 6, 12 or 24 hours in dry or humid environments
- 1, 25 or 50 reprocessing cycles
- Analysis: OPA-method

Corrosion

- 108 forceps
- Contaminated before each reprocessing cycle
- Stored for 6, 12 or 24 hours in dry or humid environments
- 1, 25 or 50 reprocessing cycles
- Analysis: Stereomicroscopy, scanning electron microscopy (SEM), and energy dispersive spectroscopy (EDS)



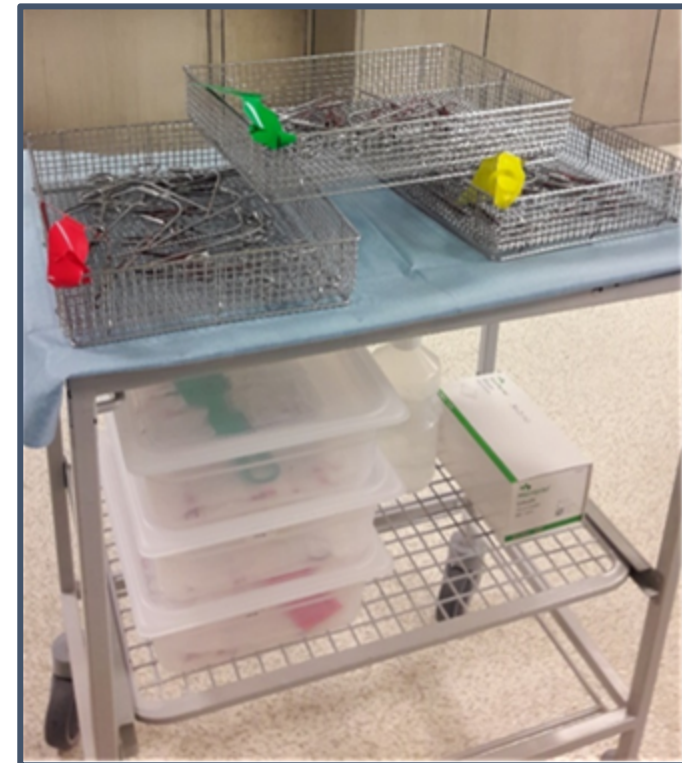
Defining storage environment

Dry

- Storage in open transport boxes without cover

Humid

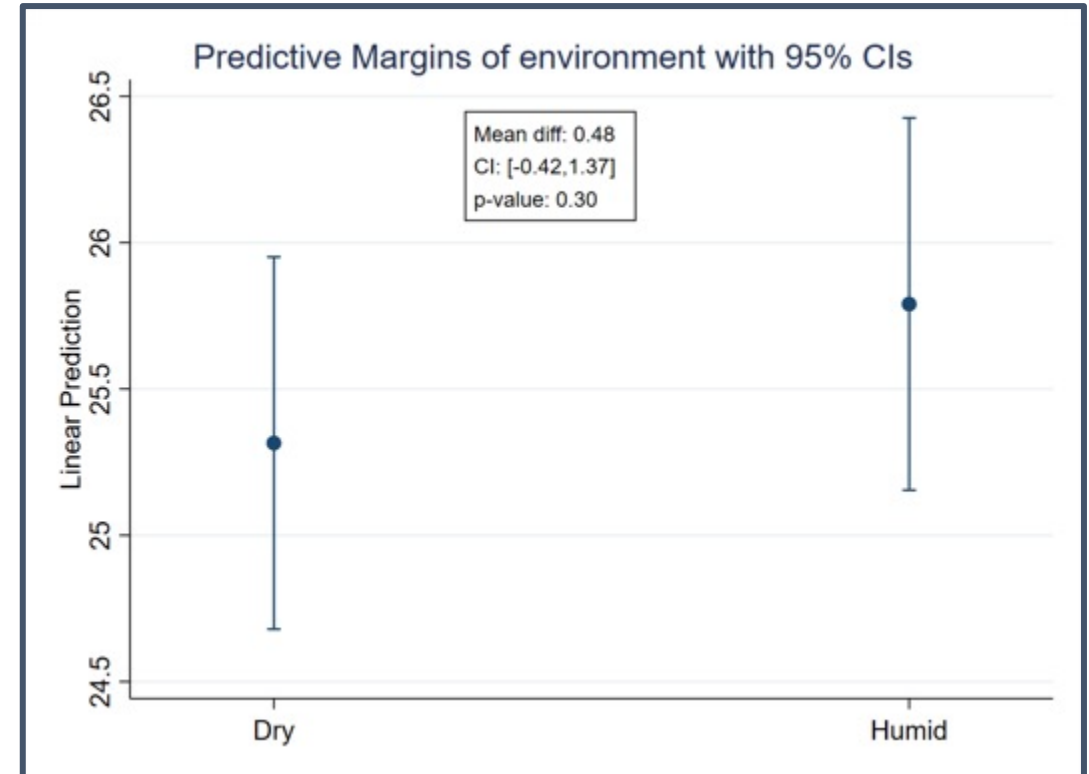
- Storage in closed transport box covered in the same amount of cotton gauze wetted with the same amount of sterile water



Results

Protein residue

- Forceps ranged from 21.8 to 28.1 μg
(mean: 24.4 μg , sd: 1.3 μg)
- Syringes ranged from 21.5 to 54.0 μg
(mean: 26.7 μg , sd: 4.9 μg)
- Negative control (mean: 24.5 μg , sd: 1.8 μg)

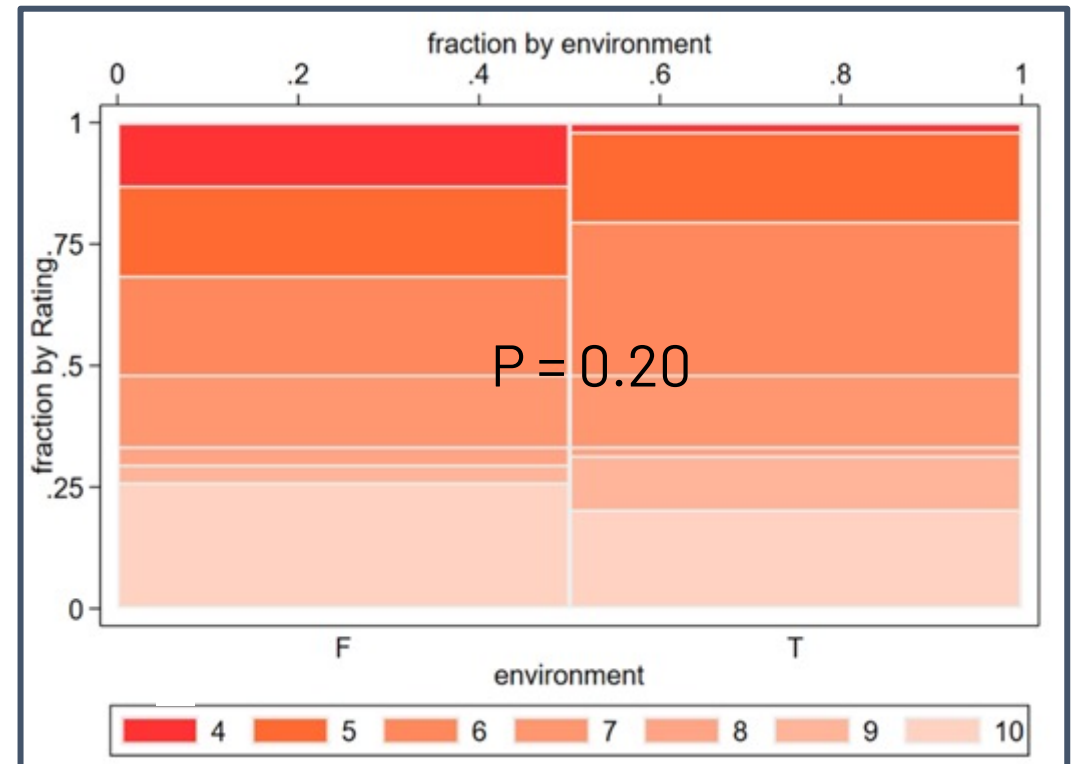


Results

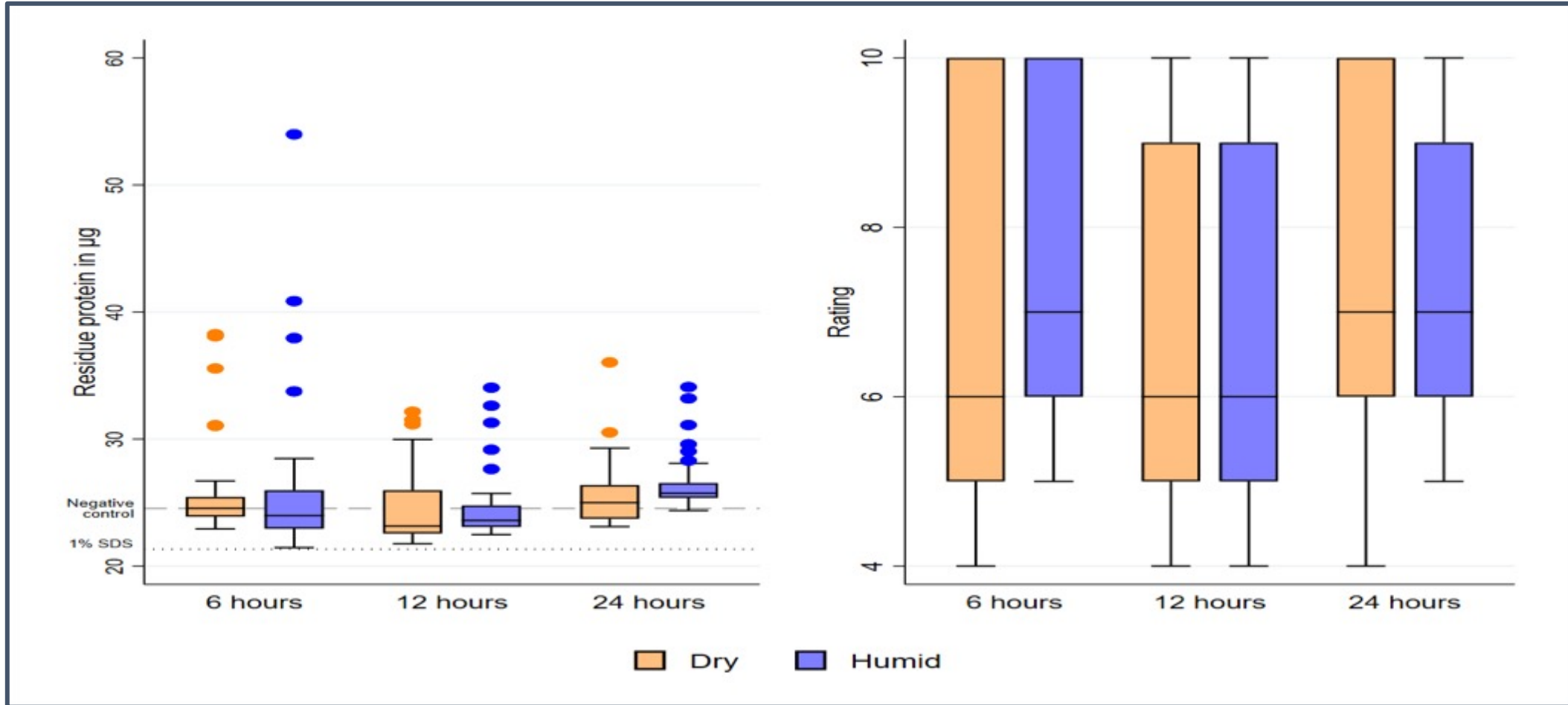
Area of corrosion, A [%]	Rating, Rp [-]
No defects*	10
$0 < A \leq 0,1$	9
$0,1 < A \leq 0,25$	8
$0,25 < A \leq 0,5$	7
$0,5 < A \leq 1,0$	6
$1,0 < A \leq 2,5$	5
$2,5 < A \leq 5,0$	4
$5,0 < A \leq 10$	3
$10 < A \leq 25$	2
$25 < A \leq 50$	1
$50 < A$	0

Corrosion

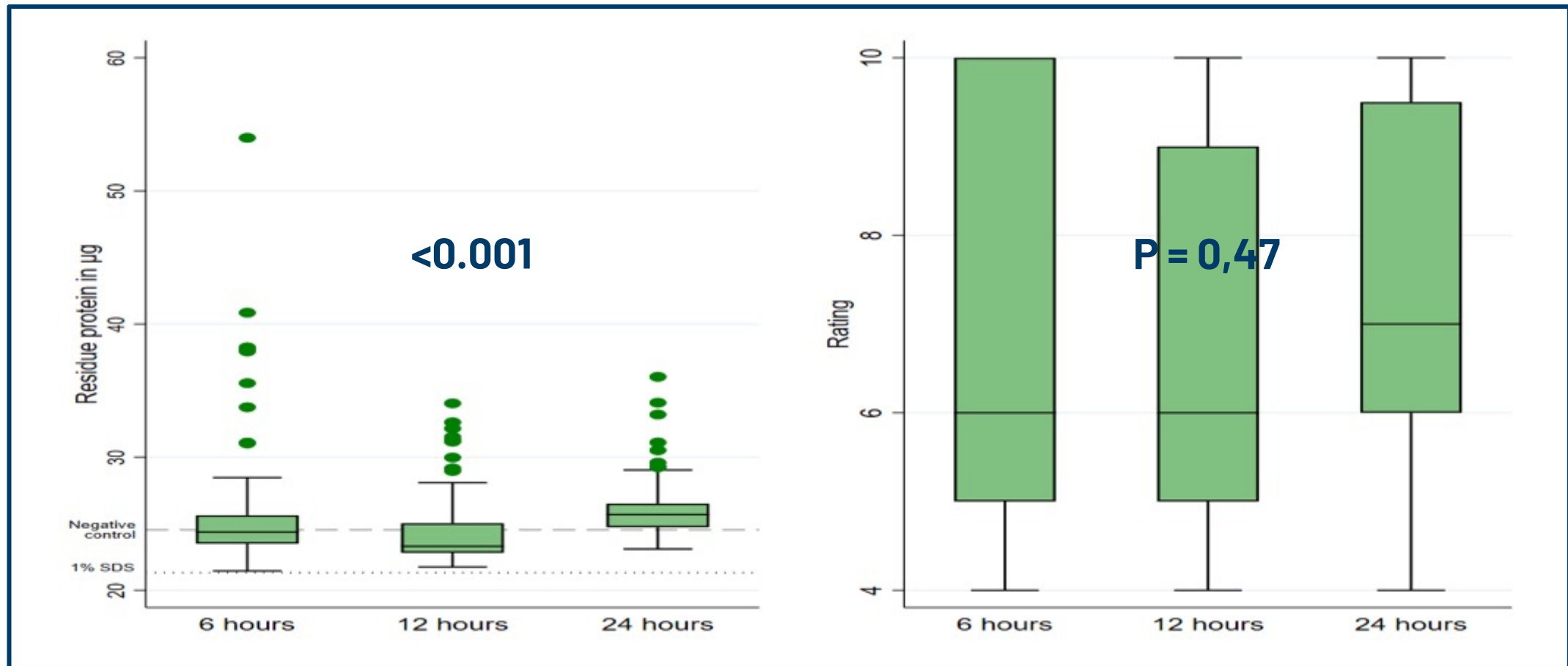
- 1 cycle: None to 0.25% (mean 0.06%)
- 25 cycles: 0.25 and 5.0% (mean 0.52%)
- 50 cycles: 0.25 and 5.0% (mean 1.45%)



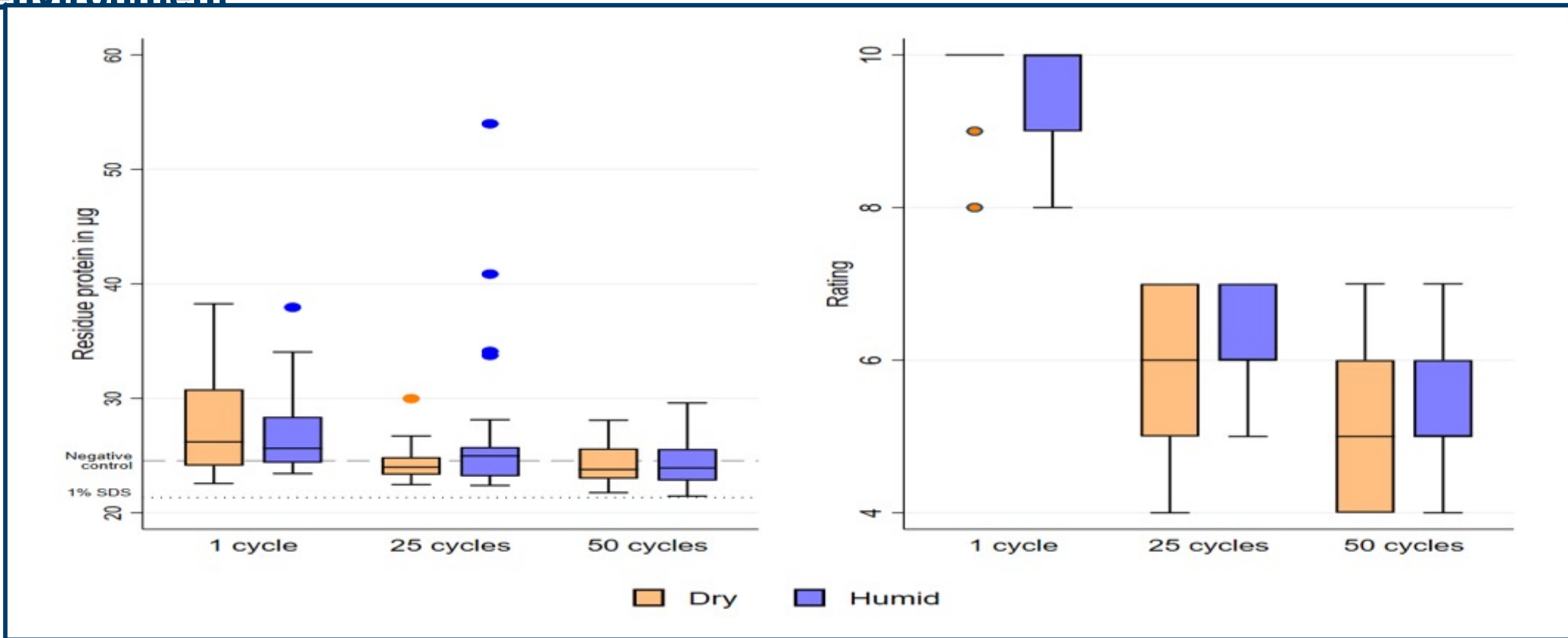
Holding time adjusted for storage



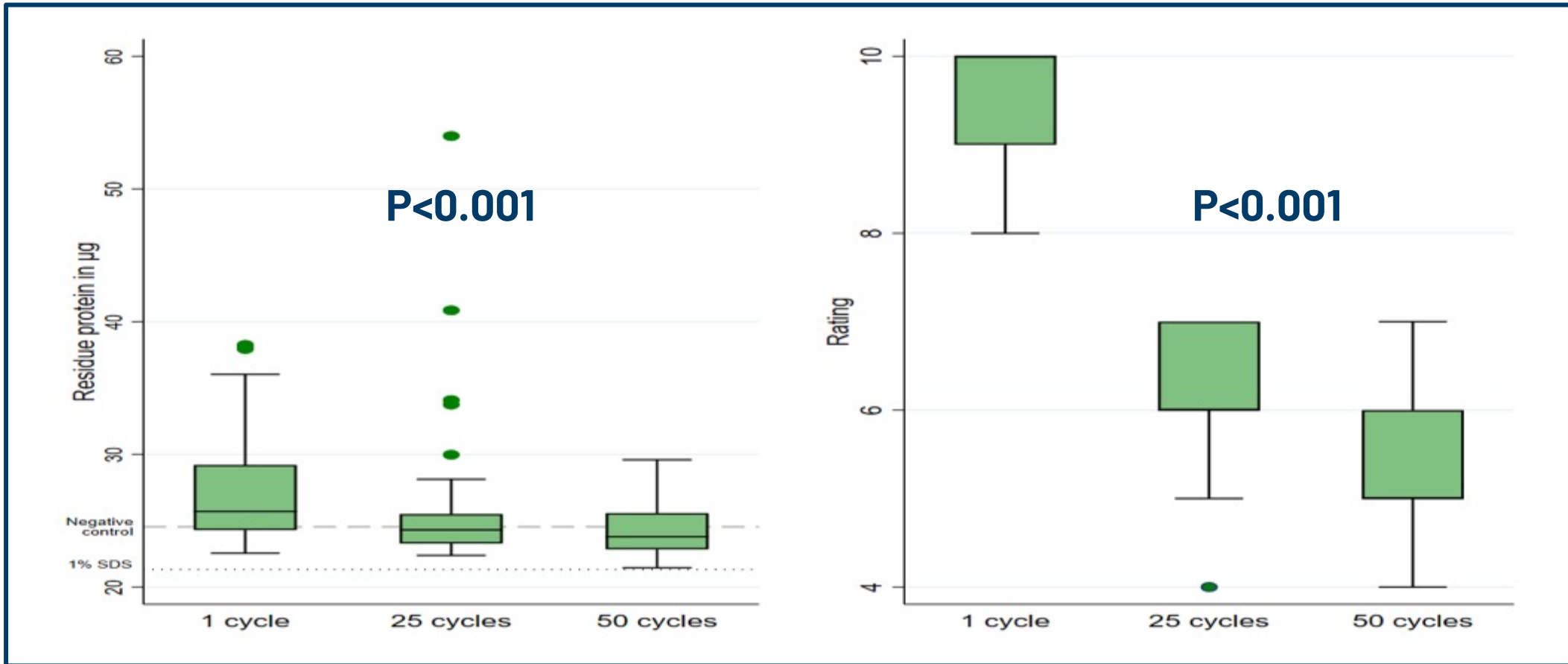
Holding time

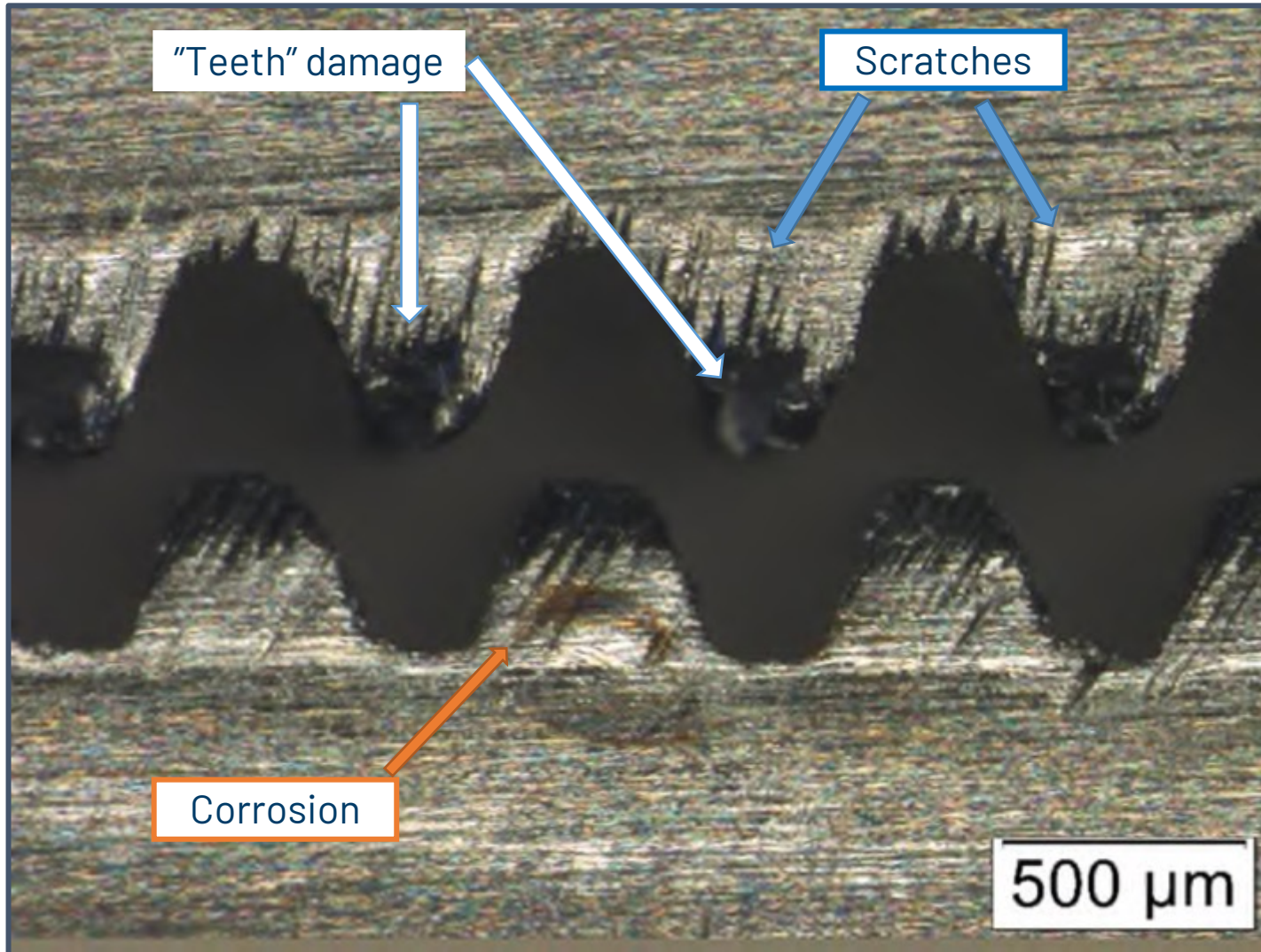


Number of cycles adjusted for storage environment



Number of





- Defects were observed on all inspected instruments
- Pitting corrosion in random areas
- EDS revealed particles consisting of silicon, calcium and aluminum
- Not caused by corrosion but likely due to the metal composition of the instruments

Conclusion

Cleanliness and durability of instruments seems not to be affected by storage environment but instead by number of treatment cycles

Patient safety seems not to be compromised by storage environment; however, it is unknown if corrosion residue are transferred from the instruments to the patient and which amount of corrosion may have a damaging effect

Strength and limitations

- Choice of instruments: Commonly used instruments for surgery
- Choice of soiling: Human EDTA blood and a common hospital bacteria strain known for its adhesiveness
- Standardized environments
- Reprocessing: Standard protocols for washing, disinfection and sterilization
- Handling of reprocessing: Trained personnel from the CDS
- Protein residue analysis: Performed by professionals – OPA method
- Corrosion analysis: Performed by professionals – provides quantification

- Choice of soiling
- Choice of method of creating a humid environment
- Choice of instruments
- ...

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Research group

- Peter Rubak, Ass. Professor, PhD, Aalborg University Hospital, Denmark
- Jan Lorenzen, Product Manager Biotechnology, PhD, Danish Technological Institute, Denmark
- Krister Ripadal, CSSD manager, MScPH, Aalborg University Hospital, Denmark
- Ann-Eva Christensen, Biostatistician, PhD, Aalborg University Hospital, Denmark
- Dorthe Aaen, Specially trained hygiene nurse, MPH, Aalborg University Hospital, Denmark
- Hans Linde Nielsen, Chief Physician, PhD, Clinical Ass. Professor, Aalborg University & Aalborg University Hospital, Denmark
- Karin Bundgaard, Ass. Professor, PhD, MScN, RN, Aalborg University & Aalborg University Hospital, Denmark

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Influence Factors of Disposal Results

Process Goals:

- Instruments clean (different limits)
- Free of stains and corrosion (Value preservation, Inspection)

Multiple Influence Factors

- Can not be fully simulated in laboratory
- No process has perfect results

Comparative clinical trials necessary

⇒ Recommendations for daily practice (depending on circumstances)

Study Groups will cooperate !

Surgery:

- Types of soil
- Degree of soiling
- Intermediate cleaning
- Geometry of devices



Point-of-Use Cleaning:

- Way of cleaning (immersion, wiping,...)
- Media (Water, Saline,...)
- Chemistry



Transportation

- Moist / Dry /....
- Time
- Temperature, humidity,...



Repeated

- Accumulation
- Long term Results

Manual Pre- Cleaning:

- Way of cleaning (Brush, Ultrasound,...)
- Media (Water, Saline,...)
- Chemistry



Machine Cleaning

- Parameters
- Media (Water, Saline,...)
- Chemistry



Inspection