



World Federation for
Hospital Sterilization Sciences

DGSV

Deutsche Gesellschaft für
Sterilgutversorgung e.V.

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WORLD CONFERENCE
CENTER FOR
CLEANING DISINFECTANTS OR
DISINFECTING CLEANERS –
what should be considered?

Processing Steps

- Cleaning
- Rinsing
- Disinfecting

Effectiveness Verification

- **Cleaner**

- No approved test methods
- No approved specifications for the efficacy
- No approved listing

Effectiveness Verification

■ **Cleaner**

- No approved test methods
- No approved specifications for the efficacy
- No approved listing

■ **Disinfectant**

- Approved test methods
- Approved specifications for the efficacy
- Approved listing (DE: VAH, RKI, DVV, DVG)

Effectiveness

Verification

- **Cleaning disinfectant / disinfecting cleaner**
 - Cleaning component
 - No approved test methods
 - No approved specifications for the efficacy
 - No approved listing

Effectiveness

Verification

- **Cleaning disinfectant / disinfecting cleaner**
 - Cleaning component
 - No approved test methods
 - No approved specifications for the efficacy
 - No approved listing
 - Disinfecting component
 - Approved test methods
 - Approved specifications for the efficacy
 - Approved listing (DE: VAH, RKI, DVV, DVG)

Effectiveness

Review

- Is peracetic acid suitable for the cleaning step of reprocessing flexible endoscopes?

Kampf G, Fliss PM, Martiny H; World J Gastrointest Endosc 2014

Effectiveness

Review – study selection process

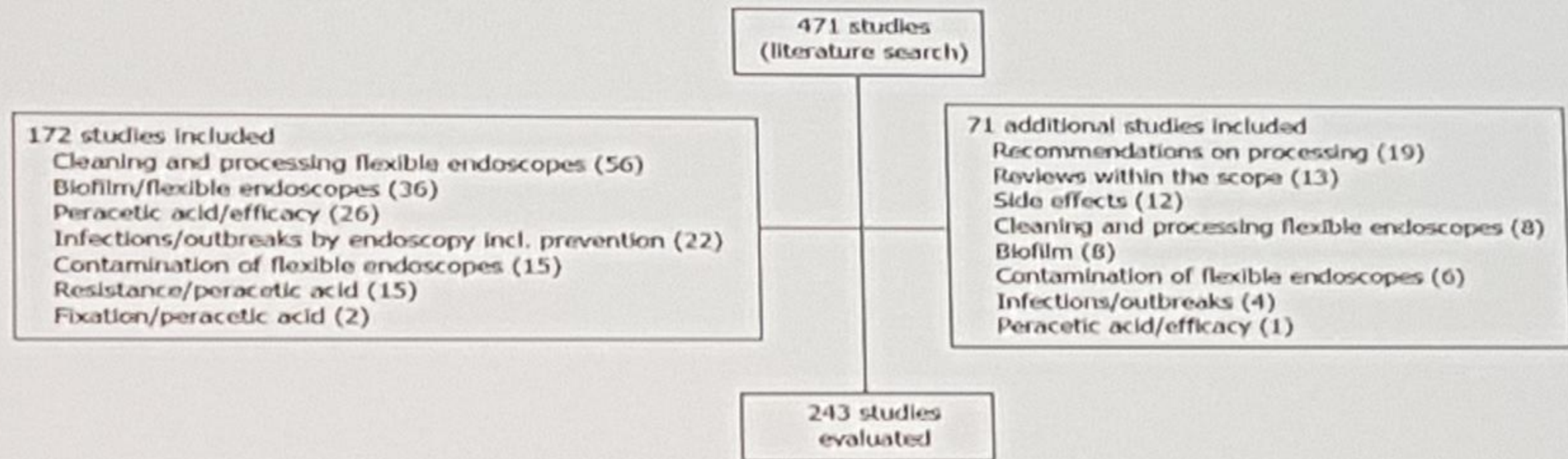


Figure 1 Flow diagram on the study selection process.

Kampf G, Fliss PM, Martiny H; World J Gastrointest Endosc 2014

Effectiveness Review – Conclusion

However, we found no conclusive evidence to suggest that the cleaning capacity of any peracetic acid-based formulation was as good as that of detergent-based cleaning agents without biocidal agents.

Kampf G, Fliss PM, Martiny H; World J Gastrointest Endosc 2014

Effectiveness of instrument disinfectants

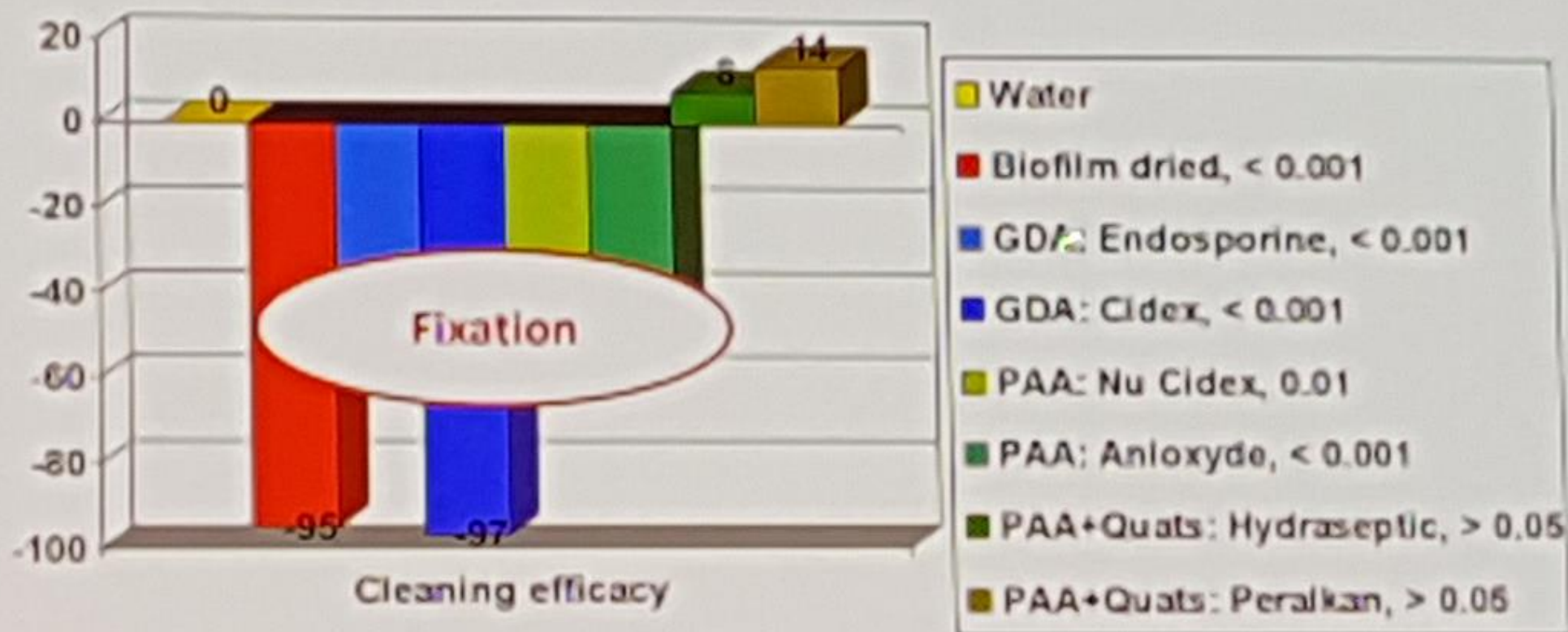
E. coli-Biofilm in glass tubes

- 6 Instrument disinfectants
 - GDA: Endosporine, Cidex
 - PAA: Nu Cidex, Anioxyde 1000, Hydraseptic, Peralkan
- *E. coli*-biofilm dried in „glass tubes“ 72 h (37°C), “glass tubes” filled, used according manufacturer informations
- Rinsed and stained with Kristall-Violett
- 3 x rinsed with water; extracted by DMSO:H₂O (1:1); detected at 600 nm

Henoun Loukili et al; Effect of peracetic acid and aldehyde disinfectants on biofilm;
J Hosp Infect 58 (2004)

Effectiveness of instrument disinfectants






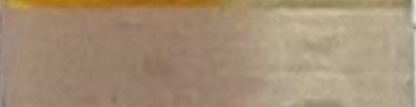


E. coli-Biofilm in glass tubes



Henoun Loukill et al; Effect of peracetic acid and aldehyde disinfectants on biofilm;
J Hosp Infect 58 (2004)

Effectiveness of instrument disinfectants

Impact on dried blood

Active agent		Process
Peracetic acid I		After disinfection
		After cleaning
Glutaraldehyde I		After disinfection
		After cleaning
QAC		After disinfection
		After cleaning
QAC + Amines		After disinfection
		After cleaning

Kampf, Bloß, Martiny, J Hosp Infect (2004)

Effectiveness of instrument disinfectants

Impact on dried blood

- Fixating
 - FAA-products
 - **92 % - 41 %**
 - GDA-products
 - **92 % - 76 %**

Kampf, Bloß, Martiny, J Hosp Infect (2004)

Active agent	Product	Removal of blood [%]
Peracetic acid	1	8,1
Peracetic acid	2	39,0
Peracetic acid	3	59,0
Peracetic acid	4	56,6
Glutaraldehyde	5	21,7
Glutaraldehyde	6	23,6
Glutaraldehyde	7	8,1
QAC	8	88,5
QAC	9	88,2
QAC + Amin	10	35,5
Phenol	11	90,3
Tensid	12	89,0

Effectiveness

Verification

■ **Instrument disinfectant**

- Required disinfecting efficacy (concentration per time)
 - Bacteria: 5 lg-steps
 - Yeasts, fungi, mycobacteria, virus: 4 lg-steps

- Organic load tested
 - Clean conditions
 - 0.03% albumin
 - Dirty conditions
 - 0.3% albumin + 0.3% sheep erythrocytes

Cleaning disinfectant / disinfecting cleaner

Organic soiling

- 3 products
 - Aldehyde + aldehyde releasing agents
 - Alkylamine
 - Alkylamine + Qac
- Hinges of Crile-clamps
 - 0.1 ml sheep blood etc + *E. faecium* 10¹⁰ CFU/ml
 - 1 h dried
 - 200 ml (each 15 min), agitated, neutralised

Gebel et al., HygMed 33 Suppl 1 (2008); Untersuchungen zur manuellen Aufbereitung medizinischer Instrumentarien;

Cleaning disinfectant / disinfecting cleaner

Organic soiling

Result

- ...The soiling represented a considerably **higher** challenge than „**dirty conditions**“ ...
- ...Despite the cleaning component the tested products did not show a sufficient disinfecting efficacy....

Gebel et al., HygMed 33 Suppl 1 (2008); Untersuchungen zur manuellen Aufbereitung medizinischer Instrumentarien;

Cleaning disinfectant / disinfecting cleaner

Organic soiling

- 5 products
 - Aldehyde, aldehyde releasing agents
 - Alkylamine derivative
 - Alkylamine, quats
 - Qac, guanidine derivative, alkylamine
 - Peracetic acid combination
- Hinges of Crile clamps and tweezers
 - sheep blood etc + *E. faecium*
 - 0, 15, 60 min dried
 - 200 ml (each 15 min), agitated, neutralised

Gebel et al., HygMed 35 Suppl 1 (2010); ESMRD: Einfluss von Blutansammlungen auf die Desinfektionsergebnisse

Cleaning disinfectant / disinfecting cleaner
Organic soiling

Result

- The reduction varied from **below 1 lg step** to a total reduction...

Gebel et al., HygMed 35 Suppl 1 (2010); ESMRD: Einfluss von Blutansammlungen auf die Desinfektionsergebnisse

Cleaning disinfectant / disinfecting cleaner

Organic soiling

- *Studies of standardisation of the manual cleaning and chemical disinfection of medical equipment.*

Patrick Haubrich,

Inaugural-Dissertation Univ. Bonn (2013)

- *Untersuchungen zur Standardisierung der manuellen Reinigung und chemischen Desinfektion von medizinischen Instrumentarien*

Cleaning disinfectant / disinfecting cleaner

Organic soiling

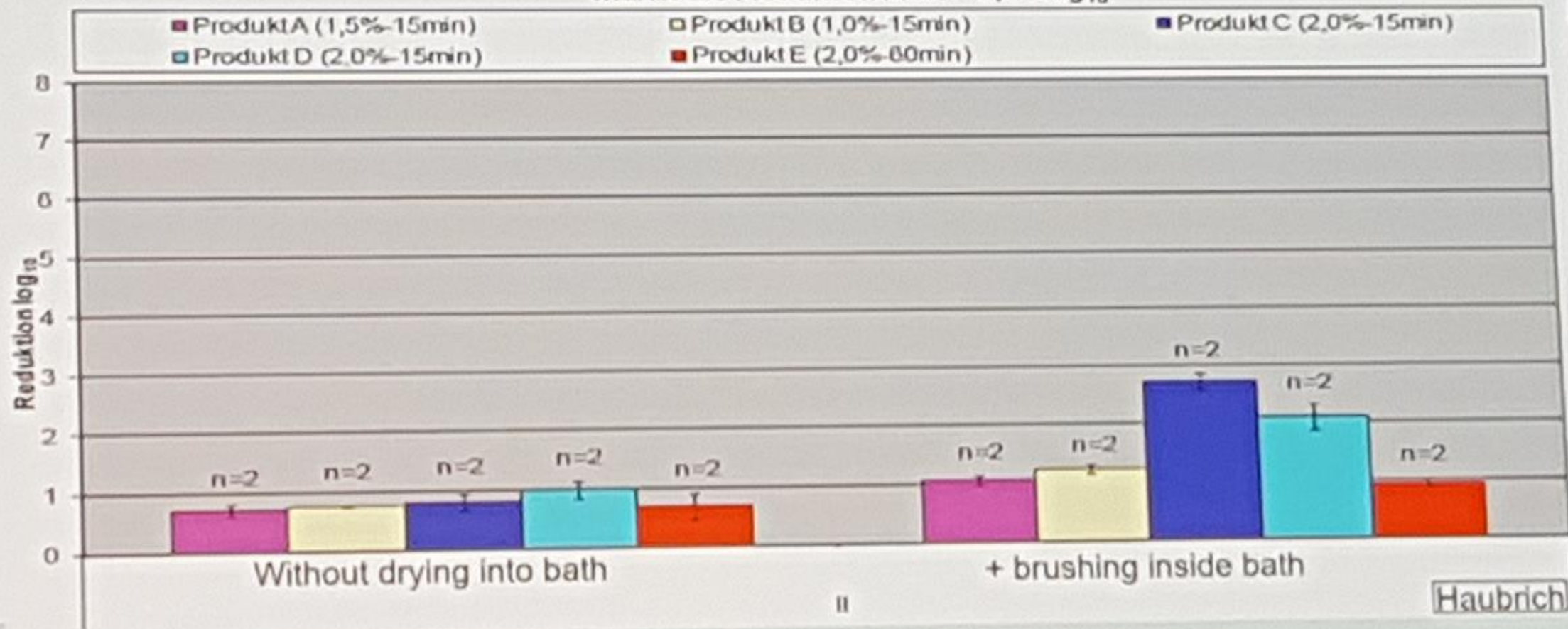
- 6 disinfectants A – F
- 4 cleaners G - J
- Test instruments
 - Crile clamps; surgical clamps; anatomic clamps
- Soiling
 - 9.5 ml heparinised sheep blood (with 10 % A. dest) with 0.35 ml *E. faecium* / *E. hirae* + protamine
 - 0.3 % albumine + 0.3 % sheep erythrozytes
- 11 different test designs

Haubrich

Cleaning disinfectant / disinfecting cleaner

Organic soiling

Testdesign II: Crile-Klemmen
Prüfanschmutzung: Schafblut + Protamin
Ausgangskonz. MW: $6,44 \log_{10} \pm 0,11$ (n=4)
maximale Reduktion MW: $> 5,44 \log_{10}$



Haubrich

Cleaning disinfectant / disinfecting cleaner

Organic soiling

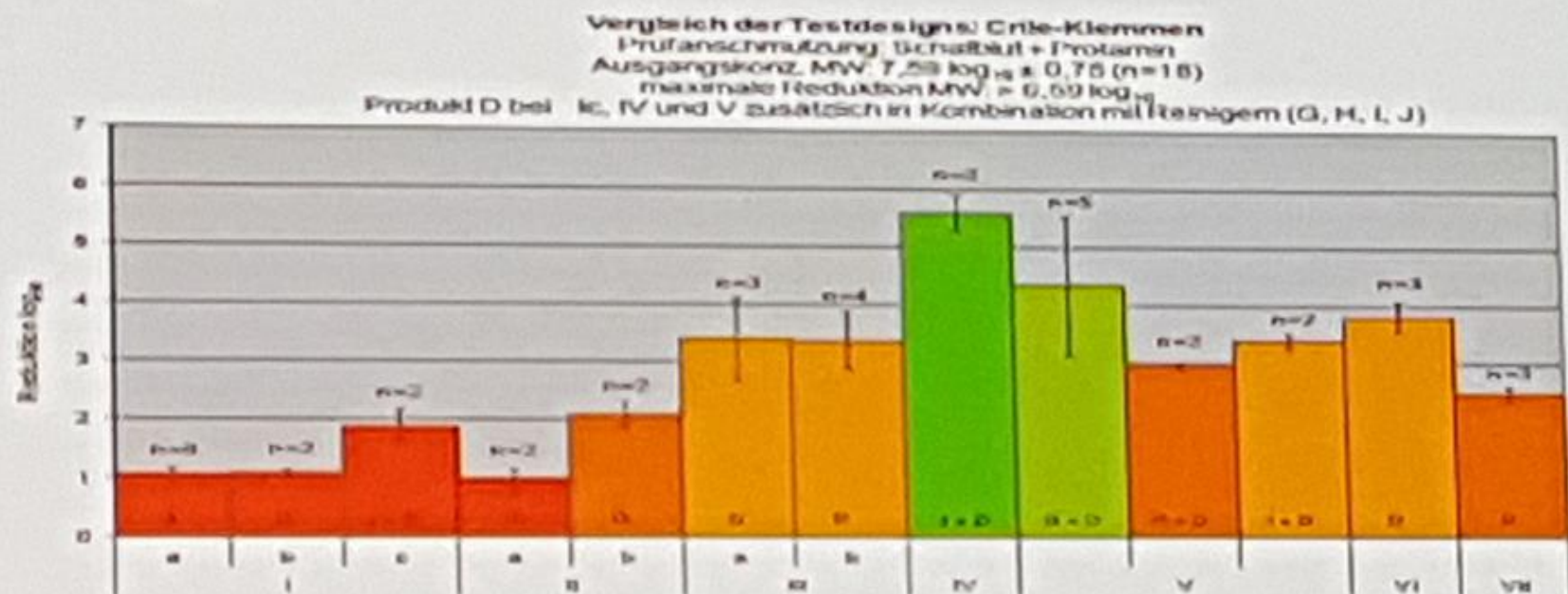


Abbildung 14: Crile-Klemmen: Vergleichende Zusammenfassung sämtlicher Testdesigns I-VII mit den entsprechenden Untergruppen für Prüfprodukt D (kam in allen Testdesigns zum Einsatz) und jeweilige Kombinationen mit Reinigern. Dargestellt sind die Mittelwerte der erzielten Reduktionen als \log_{10} -Werte, Ausgangskeimbelastung $7,59 \log_{10}$ als Mittelwert aus sämtlichen Testansätzen, Prüfanschmutzung A (Schaftblut + Protamin), jeweils mit Ultraschall bei der Rückgewinnung

■ RF 0 - 1,9 \log_{10} ■ RF 1 - 2,9 \log_{10} ■ RF 2 - 3,9 \log_{10} ■ RF 3 - 4,9 \log_{10} ■ RF 4 - 5,9 \log_{10}

Haubrich

Cleaning disinfectant / disinfecting cleaner

Organic soiling

- Result for No "D" (approved 5 lg: 2%, 15 min)
successful only with test design IV
 - Dry storage (60 min, 20° C)
 - 0.5 min rinsing with flowing tap water
 - 10 min in enzymatic cleaner „J“ incl. 2 x brushing
 - Disinfection
 - Rinsing
 - Neutralization

Haubrich

Effectiveness

Recapitulation

- **Cleaning disinfectant /disinfecting cleaner**
 - Cleaner
 - No evidence for a efficacy
 - No evidence for the extent
 - Disinfectant
 - Evidence for a efficacy
 - Evidence for the extent

Conclusion

- A **validated process** is always needed to show, that after
 - Cleaning
 - Rinsing
 - Disinfectingthe target is met:
sufficiently cleaned and disinfected items!!!!