20. WORLD STERILIZATION CONGRESS – DEN HAAG 2019

Challenging the six-hour recommendation for reprocessing sterilizable surgical instruments by identifying proportionality between protein residue and corrosion; and holding time

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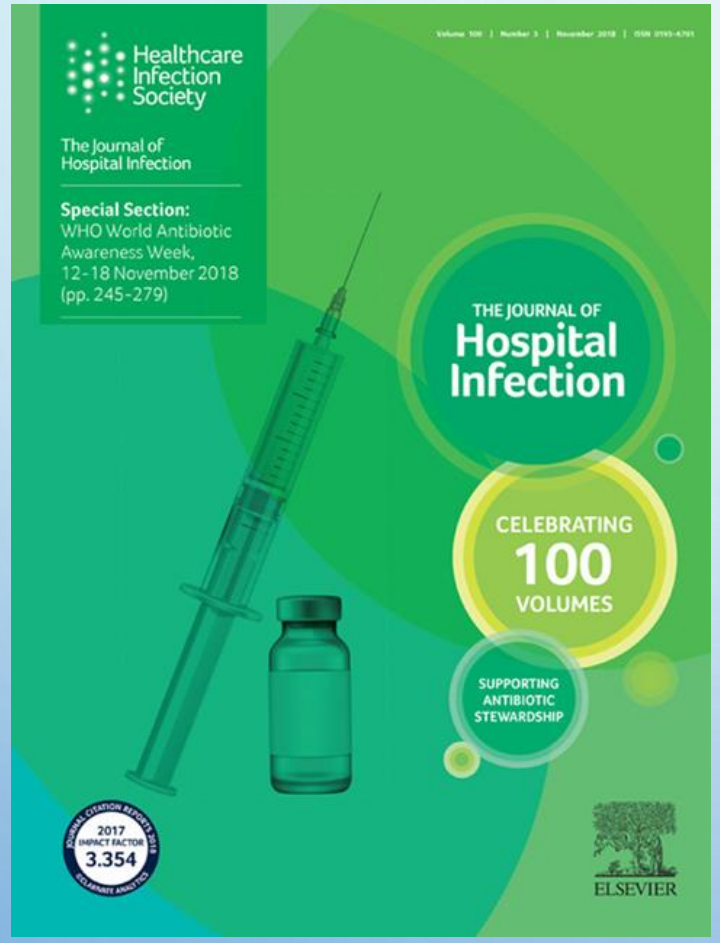

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Challenging the six-hour recommendation for reprocessing sterilizable medical equipment

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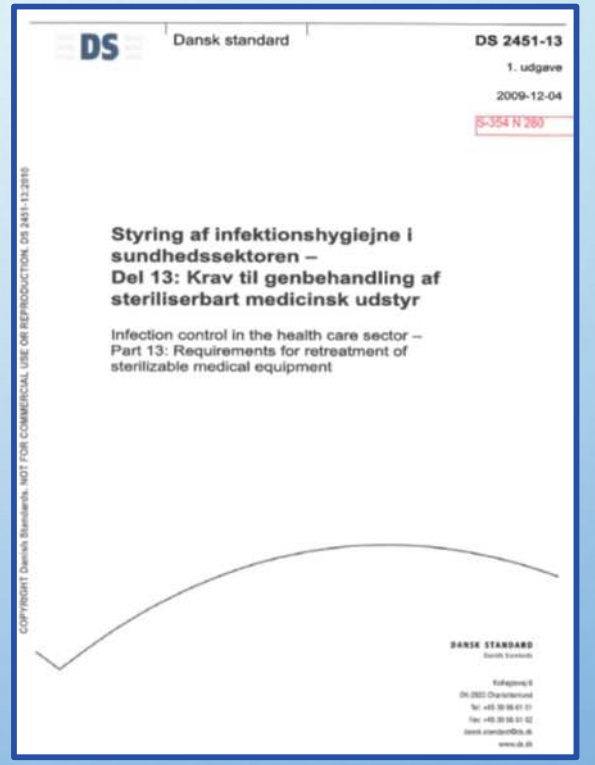
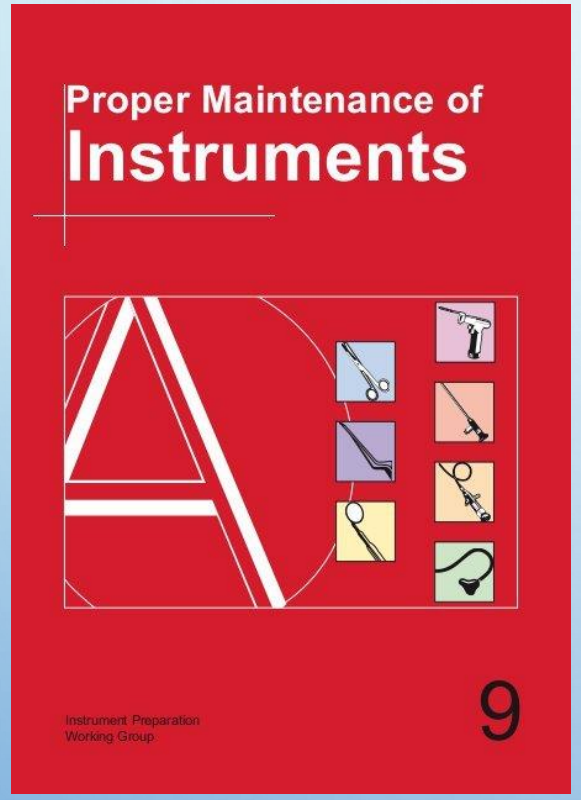
GUIDELINES AND RECOMMENDATIONS…

- National and international guidelines recommend reprocessing of sterilizable medical equipment to be initiated within 6 hours after completion of surgery
- The main concern is that a longer holding time may result in deterioration of the instruments
  - *inefficient cleaning using standard protocols for reprocessing*
  - *consequently more susceptibility to corrosion*


DS Dansk standard DS 2451-13
1. udgave
2009-12-04
Styring af infektionshygiejne i sundhedssektoren – Del 13: Krav til genbehandling af steriliserbart medicinsk udstyr
Infection control in the health care sector – Part 13: Requirements for retreatment of sterilizable medical equipment
DANSK STANDARD

DS 2451-13…



- DS 2451-13 is based on "Proper Maintenance of Instruments" recommendations published by the Instrument Preparation Working Group
- ISO 17664: 2017
- The recommendations are based on guidelines and procedural descriptions, as well as on consensus on "best practice" - limited evidence-based knowledge
- First edition published in 1979, is currently translated into 19 languages, reflecting the working group's international relevance
- The recommendations are based on guidelines and procedural descriptions from 1977-2003

WE KNOW…

- There is an increase in protein residue and bacterial load proportional to holding time before reprocessing is initiated (Secker et al. 2015, Percin et al. 2012, Mohite et al. 2016)
- Pre-soaking and temperature control while in transit between theatres and cleaning facilities may allow an increase in time before high protein adsorption levels occur (Lipscomb et al. 2007)
- Limited knowledge of the association between holding time and the cleanliness of surgical instruments after reprocessing
- A systematic review showed a very low risk of cross-transmission of infection through reusable surgical instruments if cleaning and sterilization procedures were adhered to (Southworth 2014)

WE ALSO KNOW…

- All types of stainless steel will gradually corrode and become discolored
- Surgical stainless steel consists of iron, carbon, chromium, nickel, and other metals in smaller quantities. Corrosion resistance, mechanical strength, moldeability, etc. depend on the amount and composition of these components (Rosenburg, 2016)
- A passivating thin and invisible oxide film consisting of a connection between chromium and iron oxide is formed on the surface of the instrument. The passive layer provides the metal its corrosion resistance which increases with a chromium content up to 17% (Kaiser, 2000)
- Halogen salts and especially chlorides pose a threat to the passive layer and may cause corrosion
- Corrosion range from superficial stains, discoloration integrated into the surface and pitting corrosion penetrating and destroying the surface

AIM

The aim was to evaluate the 6 hour recommendation for reprocessing sterilizable medical equipment

- *Is an increase in residual protein content proportional to holding time before reprocessing?*
- *Is an increase in corrosion present on surgical scissors proportional to holding time before reprocessing is initiated?*

METHOD - PROTEIN RESIDUE

- Scissors, knife shafts and puncture cannulae were contaminated with defribrinated human blood
- The instruments were left to dry for 0, 3, 6, 12, 24 and 36 hours at room temperature before washing in the washer-disinfector using a standard protocol
- After washing, but before disinfection, the instruments were examined for protein residue using the o-phthaldialdehyde (OPA) method

RESULTS – PROTEIN RESIDUE

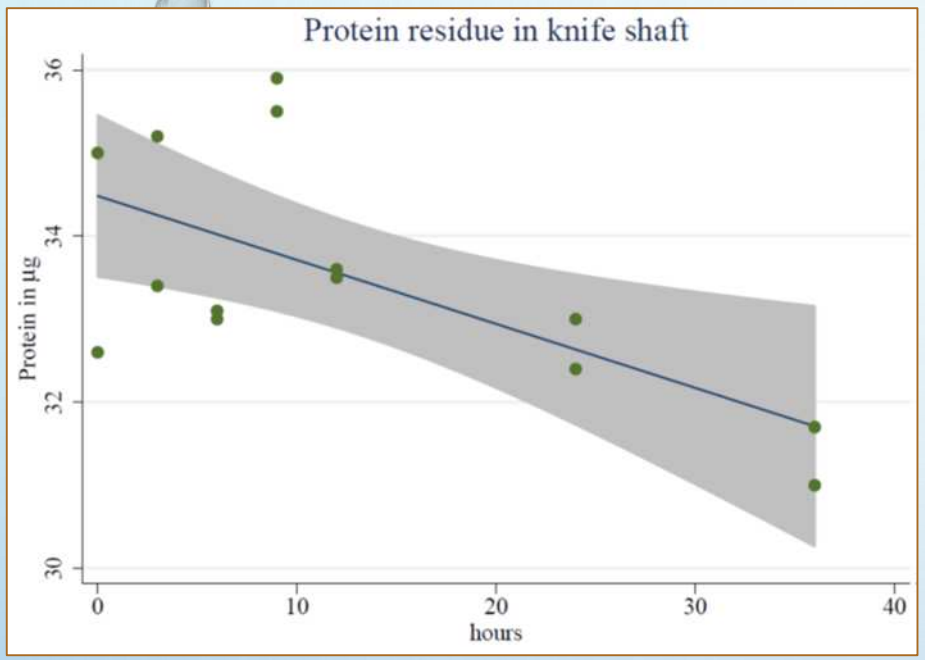
No association between protein residues and holding time before washing

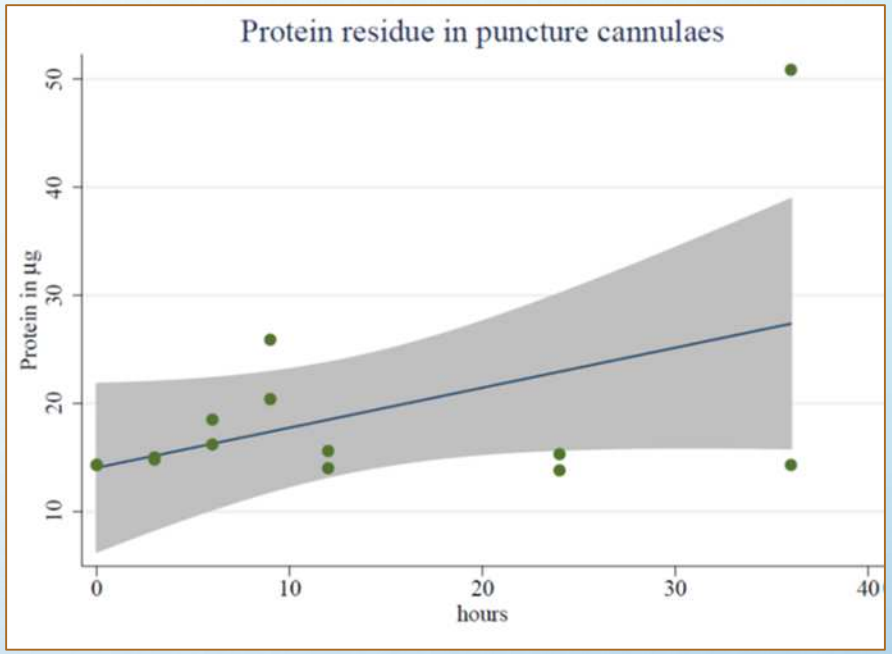
Amount of protein residues

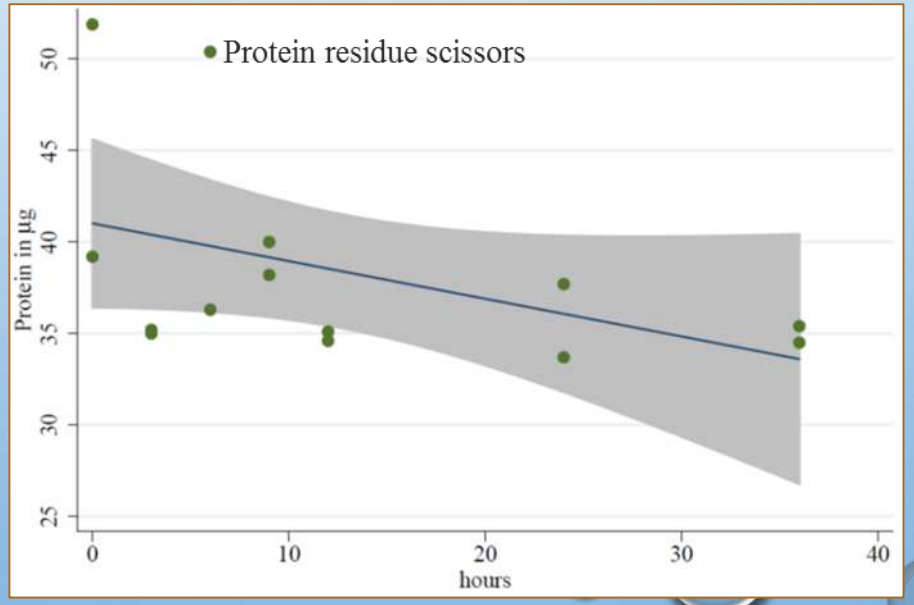
- Puncture cannulae: 14.0 µg - 50.9 µg
- Scissors: 33.7 µg - 51.9 µg
- Knife shafts: 31.0 µg - 35.9 µg

Regardless of holding time and instrument type, all protein residues were below the consensus-accepted threshold of 100 µg

Treatment	Protein µg/puncture cannulae	Protein µg/scissors	Protein µg/knife shafts
Positive Control*	>500 (794)*** >500 (1010)***	>1000 (2720)*** >1000 (2730)***	>1000 (2200)*** >1000 (2290)***
Negative control**	12,7 16,0	41,4 43,5	36,6 37,3
0 hours holding time	14,3 14,3	39,2 51,9	35,0 32,6
3 hours holding time	15,0 14,8	35,2 35,0	35,2 33,4
6 hours holding time	16,2 18,5	36,3 50,4	33,1 33,0
9 hours holding time	20,4 25,9	40,0 38,2	35,5 35,9
12 hours holding time	14,0 15,6	35,1 34,6	33,5 33,6
24 hours holding time	15,3 13,8	33,7 37,7	33,0 32,4
36 hours holding time	50,9 14,3	35,4 34,5	31,7 31,0


Protein residue in knife shaft
Protein in µg
36
34
32
30
0
10
20
30
40
hours


Protein residue in puncture cannulaes
Protein in µg
50
40
30
20
10
0
10
20
30
40
hours

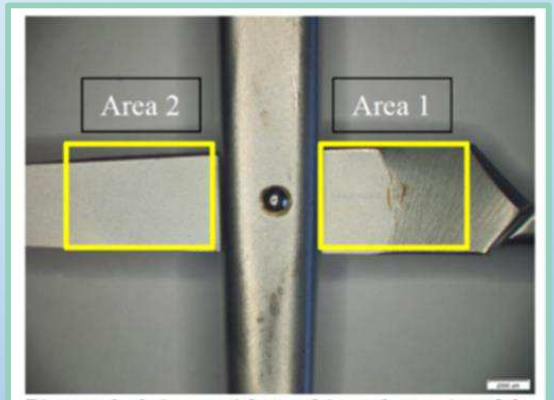

Protein residue scissors
Protein in µg
50
45
40
35
30
25
0
10
20
30
40
hours

METHOD - CORROSION

- Corrosion resistance was tested using two qualities of scissors with a chromium content of 16% and 12,5%
- The scissors were contaminated with defribrinated human blood and left to dry for 6, 12 and 24 hours, following which, they were washed, disinfected, and autoclaved
- The process from contamination to end autoclaving was repeated in the same way 50 times. The individual scissor had the same holding time throughout the test period
- Pairs of scissors of each quality subjected to each of the three holding times were tested for corrosion after 25, 35, 45, and 50 reprocessing cycles
- The scissors were examined and evaluated using light stereomicroscopy as well as electron microscopy scanning, SEM

RESULTS - CORROSION

- The scissors were examined in two areas. Analyzes were made for Area 2, because the same grade of corrosion was observed for both types of scissors for all holding times and for any number of reprocessing cycles in Area 1
- Stereomicroscopy showed surface areas with corrosion of the degree Ri 1 corresponding to 0.05% of the instrument being affected. Rating according to ISO 4628-3
- The corrodes areas were identified as red-colored deposits, lighter discolorations as well as pitting
- The surface structure of scissors with 12.5% chromium was not as smooth as the surface of scissors with 16% chromium and had small silicon embeddings (3 µm in diameter)



Picture 3: Scissor with marking of area 1 and 2.

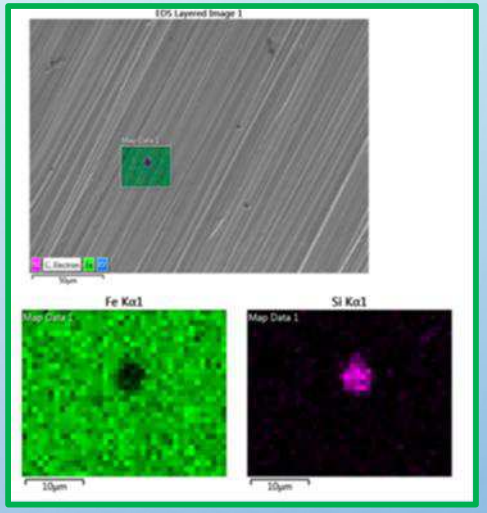
RESULTS - CORROSION

Scissors 12.5% chromium

- Same degree of corrosion was observed for scissors with 6, 12 and 24 hours holding time.
- 12 out of 15 scissors were affected
- Pitting were observed on four out of 15 scissors

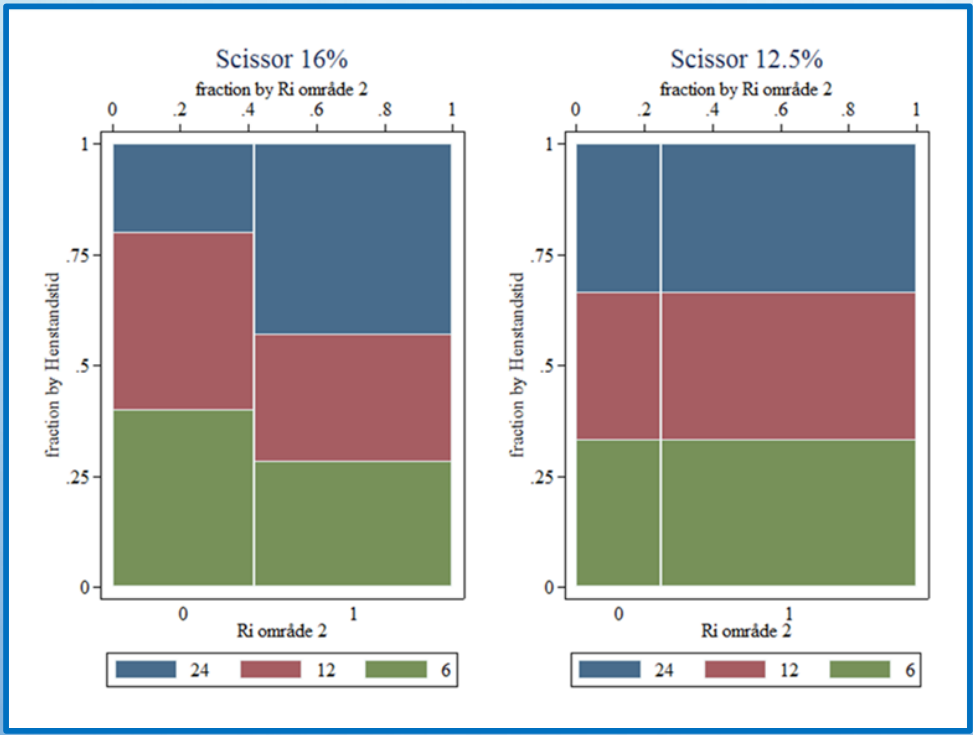
Scissors 16% chromium

- 10 out of 15 scissors were affected
- Limited and not statistically significant tendency for scissors with 24 hours holding time to be more discolored than scissors with 6 and 12 hours holding time

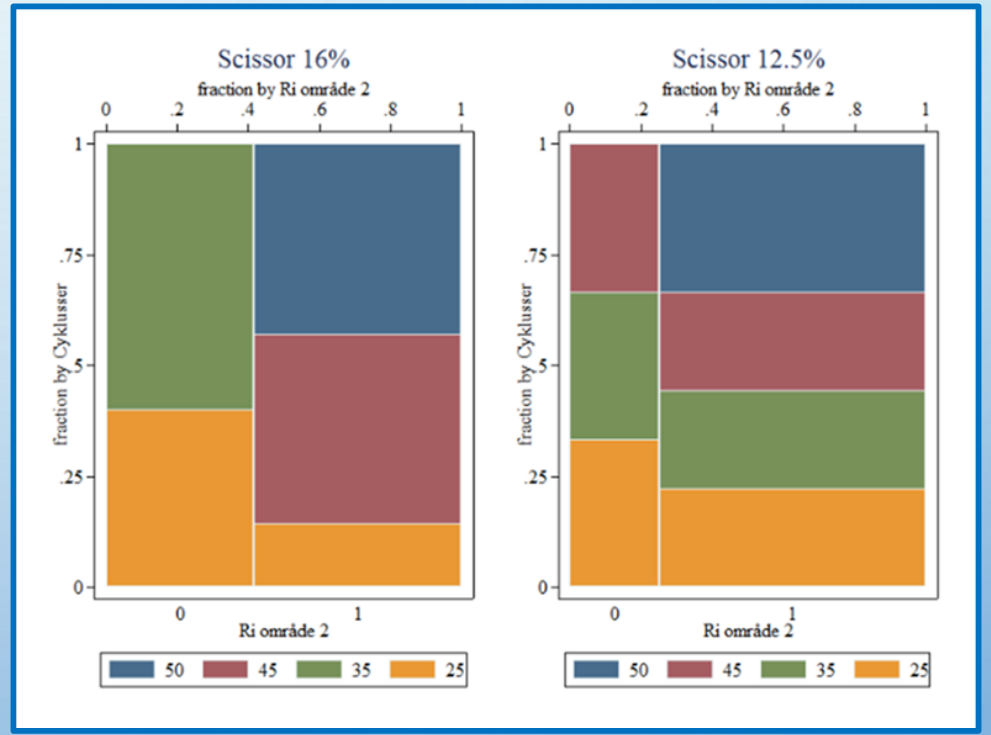


SCATTERPLOTS CORROSION

Scissors with and without corrosion in relation to holding time



Scissors with and without corrosion in relation to the number of reprocessing cycles



CONCLUSION

This study found

- no evidence that a longer holding time results in deterioration of reusable instruments
- the three instruments tested all became clean using a standard protocol for reprocessing and could have holding time up to 36 hours without the level of identified protein residues exceeding the accepted threshold of 100 µg
- less susceptible to corrosion on instruments with a high chromium content
- no evidence that two different qualities of scissors are more susceptible to corrosion when holding times exceed 6 hours

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THANK YOU