Endoscope Washer Disinfector Cleaning Process Challenge Devices – Research & Validation

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Overview

• Verification of cleaning of the internal channels of endoscopes has historically been determined using test soils in lumens of surrogate endoscopes
• The nature of these tests has always been difficult to perform, and there are significant performance differences between different soils
• A research method to test these soils, and a practical method to perform these tests on a routine basis will be described
ENDOSCOPE SOILING & PROTEINS
Endoscopes – an Unique Challenge?
‘Typical’ Endoscope?
Endoscope Soiling

• Contamination on and within endoscopes is likely to consist of:
  • Microorganisms
  • Carbohydrates
  • Proteins
  • Lipids

• Proteins will be denatured if the initial rinse temperature is too high
  • Denatured proteins are extremely difficult to remove

• Lipids require higher temperatures to aid dissolution
Proteins

- Proteins are used as a primary measure of cleaning for two reasons:
- Difficulty in removing
- TSEs
  - Transmissible spongiform encephalopathies
    - CJD
    - BSE
    - Scrapie
    - GSS (Gerstmann-Straussler-Scheinker Disease)
    - Kuru
UK and vCJD

• In the UK (since 2015) 177 deaths from vCJD
• Peak year was 2000
  – Numbers fallen progressively; no cases in 2014
• Small number of vCJD cases may have been transmitted by blood transfusion
• No known cases of vCJD being transmitted by surgical instruments or endoscopes
• Sporadic/familial CJD has been transmitted by instruments used in brain surgery
Duodenoscopes in US

Infections Associated with Reprocessed Duodenoscopes

Background

Duodenoscopes are flexible, lighted tubes that are threaded through the mouth, throat, and stomach into the top of the small intestine (duodenum). They are used during endoscopic retrograde cholangiopancreatography (ERCP), a...
Verification of Cleaning

• Is clean
  – Visibly clean?
    • Particular problems for endoscope lumens
  Or
  – Chemically clean?
Relevant Standards

- **CFPP 01-01 Part D**
  - Washer Disinfectors
  - Under revision (ACDP Guidance)

- **CFPP 01-06**
  - Endoscopy
  - Under revision (ACDP Guidance)

- **EN ISO 15883**
  - Washer disinfectors
UK Advisory Committee on Dangerous Pathogens (ACDP)

- The ACDP TSE - 5μg or less of protein *in situ on the side of any instrument tested*; lower level for high risk tissues
  - The figure of 5μg of protein has been shown to be achievable by effective cleaning processes. There is currently no definitive evidence base to link this with the absence of prion transmission risk, so lower levels for instruments making contact with high risk tissues
  - The measurement is per side of instrument rather than per unit area of an instrument. Prion proteins have been shown to be infectious by contact (Kirby et al 2012). Infection transmission would be related to the total area of an instrument that makes contact with patient tissues. Thus, whilst not a perfect relationship, the assessment of protein levels per side of an instrument is likely to be a greater predictor of risk control than an assessment based on a unit area of an instrument.
ISO 15883-4

• Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes
• 6.6 Channels non-obstruction test
• 6.11 Tests of cleaning efficacy
ISO/TS 15883-5

• Annex R

• A surrogate device for investigation of cleaning and disinfection constructed from two 1,5 m lengths of polytetrafluoroethylene (PTFE) tube with inner diameter of 2 mm and one 1,5 m length of PTFE tube having an inner diameter of 1 mm; bound together with adhesive tape
ISO 15883-5 (draft)

- **Protein**: < 6.4 μg/cm²
- **TOC** (total organic carbon): < 12 μg/cm²
- **Carbohydrate**: < 1.8 μg/cm²
- **Haemoglobin**: < 2.2 μg/cm²
- **ATP**: < 22 femtomoles/cm²
CFPP 01-06

• Currently being revised
  — Expected to be published (shortly 😊) as HTM 01-06

• Draft contains requirements for use of a periodic PCD to monitor endoscope WD cleaning performance
PROCESS CHALLENGE DEVICES (PCDs)
PCDs

• Enables verification of specific minimum performance
  – Establishes a ‘line in the sand’

• Don’t we have PCDs currently?
  – Yes; quarterly test using 2 mm and 1 mm ID PTFE tubing
Issues with PCDs – Soil Insertion

• Difficulty in injecting a viscous soil into a narrow lumen
Issues with PCDs - Elution

• While hung to ‘dry’, much soil elutes
• Hydrophobic nature of PTFE causes soil to drain under gravity
• Channel patency test in EWDs may use air or water which elutes soil without detergent
Issues with PCDs - Frequency

- Is a quarterly test appropriate to determine cleaning?
Good PCD Attributes

• Appropriate performance
  – Patient safety
• Easy to use
• Expedient
• Consistent
• Easy to interpret
Benefits of PCDs

• Can be used daily to ensure performance of EWD and its services
  – Water quality
  – Detergent

• Ensures performance of EWD in a similar way to the daily test of steam penetration (Bowie Dick test)
RESEARCH & VALIDATION
Verification Testing

• Comparative testing to surrogate soils in ISO/TS 15883-5:2005 Annex R and CFPP 01-06
• Test rig used to pass water through PTFE lumens with 3 parameters being altered (temperature, pressure (flow), detergent)
• Validated to show that HexaLumen indicators exceed performance of soil within lumen
Test Rig
Simulated Use Testing

- HexaLumen devices processed in Endoscope Washer Disinfectors with detergent
- Different users performing test cycles
- Indicators inspected following the cycles to ensure a PASS result was given
- Time recorded for different users to insert and remove indicators to ensure ease of use
STF HexaLumen™ Endoscope WD Test Kit
HexaLumen Connections

- Luer lock connectors, or use adaptors supplied in sets of 6
Channel Blockage Detection

• Alternative capsules can be used to simulate channel obstruction or blockage
• 0.5 mm capsules
• Greater restriction with use of hypodermic needles
What are the main benefits?

- Convenient
  - No messy and time consuming injection of test soil
- User friendly
  - Simple indicator capsule load and reload
- Compliant
  - Proven equivalence, to meet the surrogate device requirements of EN ISO 15883-4 & CFPP 01-06
- Safe to handle
  - No blood products
- Convenient blockage test
  - Unique flow restriction screw-in capsules
Conclusion

• Current test soils may not be optimised for cleaning of all endoscope devices
• Daily testing of endoscope WDs is important and in line with other decontamination processes such as Bowie Dick tests
• Products are available that demonstrate appropriate cleaning within endoscope channels on a daily basis
References & Further Reading

• ISO 15883-1:2006 Washer-disinfectors -- Part 1: General requirements, terms and definitions and tests
• ISO 15883-2:2006 Washer-disinfectors -- Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.
• ISO/TS 15883-5:2005 Washer-disinfectors -- Part 5: Test soils and methods for demonstrating cleaning efficacy
• CFPP 01-01 Decontamination of Surgical Instruments
• CFPP 01-06 Management and Decontamination of Flexible Endoscopes
• http://www.fda.gov/medicaldevices/productsandmedicalprocedures/reprocessingoffreusablemedicaldevices/ucm454630.htm
• Crutwell M, A Comparison of Surgical Instrument Test Soils Published in ISO/TS 15883-5 Zentr Steril 2008; 16 (4) : 256-265
Thank you! Questions?