23RD WORLD STERILIZATION CONGRESS

16TH – 19TH OF NOVEMBER 2022

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SCIENTIFIC

PROGRAM

wfhss

World Federation for Hospital Sterilisation Sciences

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23RD WORLD BARCELONA STERILIZATION CONGRESS

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AGENDA THURSDAY 17TH NOVEMBER 2022 12:30 - 14:00 CET

"H_2O_2 STERILIZATION: STANDARDS, PHYSICS, MEDICAL DEVICES AND PRACTICE." // ROOM 5

12:30h -12:35h
/ INTRODUCTION

12:35h - 12:55h
ISO 22441 AND FUTURE H_2O_2 STANDARDS
/ **Philippe Destrez**

12:55h - 13:15h
THE PHYSICS OF H_2O_2 STERILIZATION
/ **Daniel Beysens** | Represented by Assistant

13:15h - 13:35h
PROCESS VALIDATION & MEDICAL DEVICES QUALIFICATION IN PRACTICE / **Wouter Meert**

13:35h - 13:50h
/ Q&A SESSION

13:50h - 14:00h
/ CONCLUSIONS

PHILIPPE DESTREZ
R&D EMEA, ASP, STRASBOURG
MONTESSON, FRANCE

DANIEL BEYSENS
HONORARY DIRECTOR OF RESEARCHES AT THE PMMH LABORATORY
FRANCE

WOUTER MEERT
PROCESS AND PROJECT MANAGER CSSD,
UZ LEUVEN, BELGIUM

ISO 22441 AND FUTURE H_2O_2 STANDARDS

Philippe Destrez is R&D Director at ASP. He is active member of several ISO and EN standard committees including the H_2O_2 LTS working groups since their creation. He spends his all career in medical device industry and has more than 20 years of experience in device reprocessing, disinfection and prion research. He also contributed to the development of the French and WFHSS guidelines.

THE PHYSICS OF H_2O_2 STERILIZATION

Daniel Beysens is Honorary Director of Researches at the PMMH laboratory (Physique et Mécanique des Milieux Hétérogènes), a joint laboratory of CNRS (Centre National de la Recherche Scientifique) and ESPCI–PSL (Ecole Supérieure de Physique et Chimie Industrielle – Paris Sciences et Lettres). He is President - founder of the OPUR International Organization for Dew Utilization and was President of the European Low Gravity Research Association. His area of expertise is phase transition, e.g. in space, to improve the management of fluids, or to condense water from air on surfaces to provide a new source of potable water. He was awarded various prices and honors in Physics and Environmental Sciences.

ISO 22441 AND FUTURE H_2O_2 STANDARDS

Over 22 years experience in Hospital decontamination. Process, project CSA Lead. Instrument management Lead. Board member VSZ (Flemish sterilization Society). Board member VVOV (Flemish society of operating room nurses). Member of the superior health council ministry of Healthcare, infection prevention, development Belgian guidelines. Teaching sterilization courses in various schools. Member Working group, ministry of Healthcare. Management training risk analyses, ISO 13485, MDR 2017-745, International auditor. Speaker at various congresses.

23RD WORLD STERILIZATION CONGRESS

World Federation for Hospital Sterilisation Sciences

WELCOME MESSAGE

Dear friends and colleagues,

This year we will be meeting in beautiful Barcelona for a very exciting WFHSS Congress!

You will have access to a rich scientific programme based on the sharing of experiences, new technologies and will explore the major future perspectives for CSSDs such as digitalisation and questions about the carbon footprint.

And of course, the pleasure of gathering, discussing and strengthening our networks around the exhibition of our industrial partners and in all our convivial appointments!

See you soon in Barcelona

The WFHSS EC Committee

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Christine Denis – President
Carolina Chiodini
Damien Berg
Harry Oussoren
Hervé Ney

SCIENTIFIC COMMITTEE

David Bellamy – President
Christine Denis
Duygu Percin
Harry Oussoren
Patricia Gutiérrez
Vicente Zanon

POSTER JURY

Tillo Miorini – President
Duygu Percin

WEDNESDAY 16 NOVEMBER

	AUDITORIUM - PLENARY ROOM
16.00 - 18.00	OPENING OF THE REGISTRATION
18.00 - 19.00	WELCOME CEREMONY *Christine Denis*
19.00 - 21.00	**WELCOME RECEPTION IN THE EXHIBITION AREA**

THURSDAY 17 NOVEMBER

	AUDITORIUM - PLENARY ROOM	
07.45 - 08.30	**OPENING OF THE REGISTRATION AND EXHIBITION** VISIT OF POSTERS AND EXHIBITION	
	CONGRESS INTRODUCTION	
08.30 - 10.15	**SESSION 1** - SCIENCE IN STERILIZATION *Moderators: David Bellamy & Nathan Ronsse*	All the conferences will be translated in Spanish
08.30 - 09.15	CONFERENCE 1 **The physics of sterilization** *Nicolas Lavielle (France)*	
09.15 - 09.45	CONFERENCE 2 *(this session will be translated in English)* **Performance evaluation of chemical, biological and physical indicators in the process of sterilization under the effect of non-condensable gases** *Sandoval Barbosa Rodrigues (Brazil)*	
09.45 - 10.15	CONFERENCE 3 **In-depth case study of Low Temperature Steam Formaldehyde (LTSF) sterilization** *Nathan Ronsse (Belgium)*	
10.15 - 10.45	COFFEE BREAK & VISIT EXHIBITION	
10.45 - 12.15	**SESSION 2** - SCIENCE IN STERILIZATION *Moderators: Christine Denis & Michael Beekes*	All the conferences will be translated in Spanish
10.45 - 11.30	CONFERENCE 4 **Endsocopy in the 21st century: minimally invasive state of the art medical technology or a future main vector of hospital-acquired infections?** *Rodolphe Hervé (UK)*	
11.30 - 12.15	CONFERENCE 5 **Alpha-synuclein seeds of Parkinson´s disease: Transmissible biological agents with prion-exceeding resistance to steam sterilization** *Michael Beekes (Germany)*	

12.15 - 14.00	LUNCH - POSTERS AND EXHBITION		
	ROOM 6	ROOM 5	ROOM 8
12.30 - 14.00	Scientific Sponsor Meeting **PLATINUM**	Scientific Sponsor Meeting **PLATINUM**	Scientific Sponsor Meeting **GOLD**
	matachana **Reprocessing of new complex MD: challenges and remedies** **This session will be translated in Spanish*	ASP Advanced Sterilization Products **H202 sterilization: Standards, Physics, Medical Devices and Practice** **This session will be translated in Spanish*	Belimed Infection Control **Make your CSSD Smarter with Intelligent Planning, Digitalization and Innovative Training**
	AUDITORIUM - PLENARY ROOM		
14.00 - 15h30	**SESSION 3** - SPECIALIZED DECONTAMINATION *Moderators: Hervé Ney & Mary Ann Drosnock*		All the conferences will be translated in Spanish
14.00 - 14.30	CONFERENCE 6 **Validation of a cleaning verification test for lumened medical devices** *Kaumudi Kulkarni & Mary Ann Drosnock (USA)*		
14.30 - 15.00	CONFERENCE 7 **To borescope or not to borescope** *Frank Daniels (USA)*		
15.00 - 15.30	CONFERENCE 8 **Cleaning of robotic instruments: Can we reduce the work load in the CSSD and improve patient safety?** *Klaus Roth (Germany)*		
15.30 - 16.30	COFFEE BREAK & VISIT EXHIBITION		
	ROOM 9	ROOM 10	ROOM 8
15:45 - 16:30	Scientific Sponsor Meeting / **SILVER**	Scientific Sponsor Meeting / **SILVER**	Scientific Sponsor Meeting / **SILVER**
	healthmark **Inspection and Integrity Testing of Insulated Instruments: Concerns for Failure and Guidelines for Testing** **This session will be translated in Spanish*	MMM Group **Holistic RUMED solutions from one hand**	OLYMPUS **What is key to safely reprocess endoscopes?**
	AUDITORIUM - PLENARY ROOM		
16.30 - 18.00	**SESSION 4** - CLEANING EFFICACY *Moderators: Tillo Miorini & Rodolphe Herve*		All the conferences will be translated in Spanish
16.30 - 17.00	CONFERENCE 9 **New insights into chemical passivation of stainless surgical steel: Corrosion prevention and beyond** *Matthias Buhmann (Switzerland)*		
17.00 - 17.30	CONFERENCE 10 **Methods for the determination of process chemical residues after reprocessing medical devices** *Matthias Tschoerner (Germany)*		
17.30 - 18.00	CONFERENCE 11 **Statistical evaluation of protein levels of test objects and real instruments after cleaning in washer-disinfectors: Results from the years 2015 - 2022** *Karen Seekamp-Schnieder (Germany)*		

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FRIDAY 18 NOVEMBER

	AUDITORIUM - PLENARY ROOM
08.00 - 08.30	**OPENING OF THE REGISTRATION AND EXHIBITION** VISIT OF POSTERS AND EXHIBITION
08.30 - 10.15	**SESSION 5** - QUALITY IN ENDOSCOPE REPROCESSING *Moderators: Harry Oussoren & Lionel Pineau* All the conferences will be translated in Spanish
08.30 - 09.15	CONFERENCE 12 **Contributing factors on duodenoscope reprocessing and verification of interdependencies in clinical settings** *Annette Rittich (Germany)*
09.15 - 09.45	CONFERENCE 13 **Endoscope reprocessing: retrospective analysis of 90 311 samples** *Lionel Pineau (France)*
09.45 - 10.15	CONFERENCE 14 **Assesment of novel antimicrobial materials to prevent biofilm formation in critical and semi-criticat medical devices** *William Leiva (USA)*
10.15 - 10.45	COFFEE BREAK & VISIT EXHIBITION
10.45 - 12.15	**SESSION 6** - MONITORING THE EFFECTIVENESS OF STERILIZATION *Moderators: David Bellamy & Francesco Tessarolo* All the conferences will be translated in Spanish
10.45 - 11.15	CONFERENCE 15 **Implementing an evidence based parametric load release for steam sterilisation in practice** *Anke van Rosmalen (Netherlands)*
11.15 - 11.45	CONFERENCE 16 *(this session will be translated in English)* **Effectiveness of disinfection and sterilization in laparoscopes and arthroscopes and their risk of infection: a systematic review** *Sandra Patricia Rodríguez Bonilla (Colombia)*
11.45 - 12.15	CONFERENCE 17 **Monitoring steam penetration in channeled instruments: an evidence-based worst-case for practical situations** *Francesco Tessarolo (Italy)*
12.15 - 14.00	LUNCH - POSTERS AND EXHBITION

	ROOM 6	ROOM 5	ROOM 8
12.30 - 14.00	Scientific Sponsor Meeting **PLATINUM**	Scientific Sponsor Meeting **GOLD**	Scientific Sponsor Meeting **GOLD**
	Steelco **360° on conservation of utilities & instrument life whilst improving safety and CSSD working environment**	B BRAUN SHARING EXPERTISE **Sustainability in sterile supply management? Quick wins with the Aesculap Sterile Container System** *English from 12:30 to 13:15* *Spanish from 13h15 to 14:00*	GETINGE PASSION FOR LIFE **Improve your sterilization workflow for better performance and cost saving** **This session will be translated in Spanish*

	AUDITORIUM - PLENARY ROOM
14.00 - 15h30	**SESSION 7** - QUALITY MANAGEMENT *Moderator: Damien Berg & Olivier Willième* All the conferences will be translated in Spanish
14.00 - 14.30	CONFERENCE 18 **Individual surgical instrument traceability: in line with the European regulation MDR 2017/745/EU** *François Barbier (France)*
14.30 - 15.00	CONFERENCE 19 **Improvement of management efficiency by verifying the expiration date of sterilized products** *Youngsook IM (Republic of Korea)*
15.00 - 15.30	CONFERENCE 20 **Modeling a tool for planning a new CSSD** *Olivier Willième (Belgium)*
15:30 - 16:15	POSTER AWARD SESSION *Tillo Miorini*
16:15 - 16:45	COFFEE BREAK & VISIT EXHIBITION
	CONGRESS DINNER

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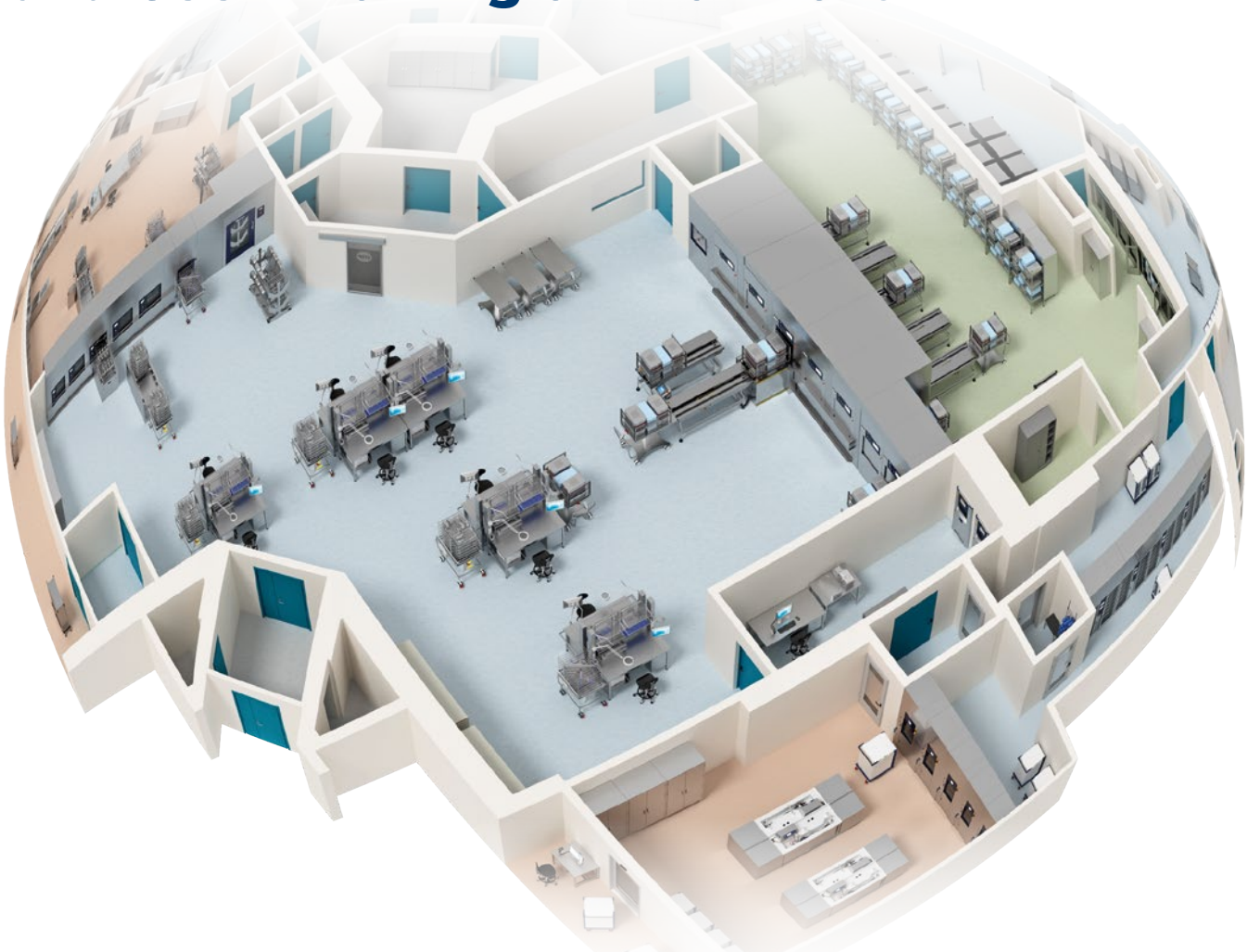
360° overview

on conservation of utilities & instrument life whilst improving safety and CSSD working environment.

Satellite Symposium
Friday, November 18th,
12:30 - 14:00 PM | Room 6



Only an approach that considers the entire sterilization process allows the discovery and exploitation of new areas of improvement in safety, efficacy, and efficiency. The benefits of the latest technologies seen from a "green" perspective.

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Hall 1, Booth 53

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SATURDAY 19 NOVEMBER

	AUDITORIUM - PLENARY ROOM
08.30 - 09:00	**OPENING OF THE REGISTRATION AND EXHIBITION** VISIT OF POSTERS AND EXHIBITION
	INTRODUCTION
09.00 - 10h30	**SESSION 8** - IMPACTS OF REPROCESSING *Moderator: Carolina Chiodini & Dayane de Melo Costa* All the conferences will be translated in Spanish
09.00 - 09.30	CONFERENCE 21 **Contamination and surface damage on reprocessed robotic system surgical instruments in clinical use** *Dayane de Melo Costa (Australia)*
09.30 - 10.00	CONFERENCE 22 **The impact of time and environmental conditions on contaminated instrumentation** *Terra Kremer (USA)*
10.00 - 10.30	CONFERENCE 23 **Investigation of the Release of Particles During Phacoemulsification Procedures** *Sulisti Holmes (Scotland)*
10.30 - 11.00	COFFEE BREAK & VISIT EXHIBITION
11.00 - 12.00	**SESSION 9** - SAFE AND SUSTAINABLE DEPARTMENT *Moderators: Patricia Gutierrez & Isabelle de la Charlerie* All the conferences will be translated in Spanish
11.00 - 11.30	CONFERENCE 24 **Sustainable development in sterilization departments** *Mayra Samara Ordoñez Diaz*
11.30 - 12.00	CONFERENCE 25 *(this session will be translated in English)* **Safety within the RUMED. Debunking myths** *Mercedes García-Haro*
12:00-12:45	**AWARDS CEREMONY & CLOSING CEREMONY** GREEN CSSD CONTEST WINNER *Harry Oussoren*
	END OF THE CONGRESS

THE PHYSICS OF STERILIZATION

PRESENTER

Nicolas Lavielle

France

AIM

Sterilization process is commonly characterized by variables such as pressure, temperature, time, humidity, concentration of the sterilizing agent and corresponding parameters ranges. However, variables are measured at chamber or load level i.e. at distance from the surfaces and microorganisms that they may carry. Entering into the intimacy of steam and low temperature sterilization process implies a closer look to surface phenomena, in particular on the role of condensation, adsorption and the presence of non-condensable gases.

METHODS

The laws of physics will be used to illustrate the complexity of interactions between the sterilizing agent and the germs according to the nature and geometry of surfaces of the medical devices. A case study with H2O2 at atmospheric pressure and low concentration will be used as a slow motion of event taking place on sterilizer chamber initially in vacuum and at high H2O2 concentration. It permits the analysis of events which are too fast in the latter configuration. Observations by micro-zoom and high precision balance are correlated with germs inactivation kinetic.

RESULTS

The law of physics tells that condensation and or enhanced adsorption phenomena are required to obtain inactivation of germs. However, the mean by which condensation/ adsorption acts differs between saturated steam at high temperature and low temperature chemical processes such as ethylene oxide, low temperature steam formaldehyde and hydrogen peroxide. Concerning more specifically H2O2, the case study with low concentration H2O2 at high pressure indicates that microbial efficacy increases at low initial relative humidity. This condition limits the thickness of the H2O2/water condensate and allows the H2O2 concentration to be higher. The interaction between the sterilizing agent and the inoculum is well visualized by the micro-zoom and correlated to inactivation kinetic.

CONCLUSIONS

Specific measurements of condensed / adsorbed mass and micro-zoom observation confirm the importance of the processes of enhanced adsorption and condensation in a sterilization process. The way in which such condensation / adsorption phenomena occur and contribute to germs inactivation differ between heat and chemical sterilization processes and even between chemical processes. However, surface phenomena are complex and highly dependent on the hydrophilicity or microporosity of surfaces or inoculum. Given the variety and increasing complexity of modern medical devices, it is hence difficult to avoid empiric microbial evaluation to assess the efficacy of a given sterilization process.

References / Acknowledgements

The research at atmospheric pressure H2O2 (2012) has been funded by ASP

World Sterilization Congress 2022

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Symposium

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PERFORMANCE EVALUATION OF CHEMICAL, BIOLOGICAL AND PHYSICAL INDICATORS IN THE PROCESS OF STERILIZATION UNDER THE EFFECT OF NON-CONDENSABLE GASES

PRESENTER

Sandoval Barbosa Rodrigues

Brazil

AIM

The risk concerning the presence of non-condensable gases (NCGs) has already been demonstrated, but routine monitoring still requires further research to be implemented in each sterilization cycle.

The aim of this study was to evaluate the performance of the physical, chemical and biological indicators used in monitoring in comparison with a sterilizer integrated detector for NCG in the Sterilization Process.

METHODS

Chemical indicators (type 2 Bowie and Dick test, type 5 and type 6 models), self contained biological indicators and physical indicators (temperature, pressure, thermal qualification and a patented integrated air detector) were used to monitor the steam sterilization process in two situations of controlled failure: chamber leakage and door seal failure. This controlled failure was obtained by the presence of a known amount of air: 0 – 30 L/min for chamber leakage and 0 - 30% for the door seal failure. Evaluation tests were carried out with and without the use of process challenge devices (PCDs).

RESULTS

In both studies, the Bowie-Dick test showed different results, according to the manufacturer, although validated based on the same technical standard. The biological, chemical and physical indicators positioned individually in the chamber, including thermal distribution, were not able to identify the NCGs in the chamber.

Conversely, the air detector, leak test and thermal qualification in the steam penetration study detected the simulated failure from the first air injection.

CONCLUSION

The integrated air detector can be considered an option for the detection of NCGs in each cycle.

IN-DEPTH CASE STUDY OF LOW TEMPERATURE STEAM FORMALDEHYDE (LTSF) STERILIZATION

PRESENTER

Nathan Ronsse [1]

CO-AUTHORS

Krist Henrotin [2]

Wouter Meert [3]

Alejandro Ramirez [4]

[1] *Hospithera - Anderlecht (Belgium)*

[2] *Uz Gent - Gent (Belgium)*

[3] *Uz Leuven - Leuven (Belgium)*

[4] *Uz Leuven - Barcelona (Spain)*

AIM

Low Temperature Steam Formaldehyde (LTSF) sterilization is a sterilization method that is currently not used in Belgium, mainly due to the negative connotation. Recent developments have however led to a safe device that can be used in CSSD and AER departments. Proof for this is the compliance to regulations EN14180, ISO25424 and EU directive 2019/983 on one hand, and on the other hand the widespread use in Spain, Germany and Asia.
Therefore, we have conducted a thorough case study with this technology in two of the biggest hospitals of Belgium. The two main goals were to investigate the performance of the technology, and to evaluate the integrability of the device in the daily routine of the CSSD. As a reference, the results of the study were also compared with hydrogen peroxide sterilization (which is a technology that is very often used in Belgium).

METHODS

Several test cycles were performed by the test users. The cycles were monitored by checking the data on the printouts (statistics processed with dedicated software), by the results of the type 2 chemical indicators in helixes, by type 4 chemical indicators in the packages, and by biological indicators. All this testing was done according to an approved test protocol.

RESULTS

The most important results are the following three points. 1) The cost of a cycle (consumables, utilities, ...) is lower when sterilizing with the low temperature steam formaldehyde method. 2) There are more possibilities / less limits with regards to the load that can be sterilized with the low temperature steam formaldehyde process. 3) With the low temperature steam formaldehyde technology, the length of a sterilization cycle is longer, which might impose certain restrictions.
Besides these points, there were also different inoculation tests performed. For example: we have biologically tested a surrogate endoscope that represents a worst-case load in terms of lumens. Worst-case loads in terms of weight were also processed. Finally, also the user friendliness of the tested device was evaluated by all the test users.

CONCLUSIONS

The conclusion of this study is that the LTSF technology can absolutely have an important place in the Belgian CSSD and/or AER departments, mainly thanks to the wide sterilization options and lower cycle cost. It is however important to consider the limitations, so that the device is used in a smart way. When properly introduced and well considered, the addition of a Low Temperature Steam Formaldehyde device to a CSSD and/or AER increases the efficiency of the department.

References / Acknowledgements

The device ("130LF") and consumables were provided by Matachana (Spain). Matachana also provided training of the test users and validation of the device after installation. The technicians for installation and maintenance were provided by Hospithera (Belgium).

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Sustainability in sterile supply management? Quick wins with the Aesculap Sterile Container System.

November 18, 2022
12:30 - 13:15, Room 5

¿Sostenibilidad en la gestión de suministros estériles? Beneficios rápidos con el sistema de contenedores para esterilización Aesculap.

18 de noviembre, 2022
13:15 - 14:00, Sala 5

Speakers: Christian Nufer, Product Manager Sterile Technology, Aesculap AG
Eva Streit, Senior Product Manager Sterile Technology, Aesculap AG

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ENDOSCOPY IN THE TWENTY-FIRST CENTURY: MINIMALLY INVASIVE STATE-OF-THE-ART MEDICAL TECHNOLOGY OR A FUTURE MAIN VECTOR OF HOSPITAL-ACQUIRED INFECTIONS?

PRESENTER

› **Rodolphe Hervé**

› **AIM**

Endoscopes were originally developed as simple optical instruments, which may explain their classification as "semi-critical devices" according to Spaulding back in the 1960's. However, luminal flexible endoscopes have become versatile tools commonly used worldwide for routine diagnostic examinations, as well as increasingly complex surgical procedures involving a range of specialized instrumentation breaking through the patients' mucosal barrier. We evaluated the current status of flexible luminal endoscopes and issues surrounding their clinical use and reprocessing. We are also examining the potential of the latest developments in cold atmospheric plasma for the reprocessing of these instruments.

› **METHODS**

We used highly sensitive fluorescence epi-microscopy to examine the various surfaces of endoscopes, particularly the luminal surface of working channels.

› **RESULTS**

Chemical-based high level disinfection has known limits despite adherence to recommended cleaning protocols, to the point that residual micro-organisms remain tolerated according to standards which vary between locations. Our studies demonstrated the accumulation of "historical" soil in endoscope channels other several years of clinical use, as well as residual biofilms having survived reprocessing cycles.

› **CONCLUSIONS**

The problem of antimicrobial resistance is developing faster than new drugs are emerging. Consequently, fatal cases of hospital acquired infections linked to reusable endoscopes have been identified and reported in the literature, though these may only be the "tip of the iceberg". This warrants further research and development in the field of endoscopes reprocessing and surveillance to maintain trust among the patients and practitioners that the benefits of endoscopic examinations and/or interventions still significantly outweigh any risks in the coming decades.

References / Acknowledgements

Hervé and Keevil (2016, Endoscopy)

ALPHA-SYNUCLEIN SEEDS OF PARKINSON´S DISEASE: TRANSMISSIBLE BIOLOGICAL AGENTS WITH PRION-EXCEEDING RESISTANCE TO STEAM STERILIZATION

PRESENTER
Michael Beekes

Cerebral deposition of abnormally misfolded and aggregated alpha-synuclein (αSyn) is a neuropathological hallmark of Parkinson´s disease (PD). Pathologically aggregated αSyn species of PD (αSynPD) can act as proteinaceous nuclei ('seeds') which are able of self-templated propagation. Since this is strikingly reminiscent to properties of proteinaceous infectious particles (prions), lessons learned from prion diseases suggest to test whether transferred αSynPD can propagate and induce neurological impairments or disease in a new host.

To advance the assessment of such theoretically conceivable αSynPD hazards we examined neuropathological and clinical effects upon intracerebral injection of brain, stomach wall and muscle tissue homogenates as well as blood from PD patients in transgenic TgM83+/- mice hemizygously expressing mutated (A53T) human αSyn up to 612 days post injection (dpi).

This revealed a subtle, yet distinctive stimulation of localized αSyn aggregation in the somatodendritic compartment and dystrophic neurites of individual or focally clustered cerebral neurons after challenge with brain and stomach wall homogenates. No such effect was observed with transmitted blood or homogenized muscle tissue. The detected stimulation of αSyn aggregation was not accompanied by apparent motor impairments or overt neurological disease in TgM83+/- mice.

Our study substantiated that transmitted αSynPD seeds, including those from the stomach wall, are able to propagate in new mammalian hosts. The consequences of such propagation and potential safeguards need to be further investigated. This holds particularly true with respect to concerns that αSynPD seeds iatrogenically transmitted between humans may stimulate αSyn pathologies or clinically harmful effects in recipients. Effective decontamination when reprocessing medical devices could significantly counteract such theoretical risks. Steam sterilization at 134° C is recommended as an essential pathogen inactivation step in many reprocessing guidelines for medical devices and shows effectiveness also against prions, the self-propagating biological agents long thought to exhibit the highest resistance to steam sterilization.

Therefore, we examined the reduction of αSynPD seeding activity in brain tissue homogenates from PD patients after steam sterilization at 134°C using a specifically adapted real-time quaking induced conversion (RT-QuIC) assay. We detected titres of about 1010 50% seeding doses (SD50) per gram in non-steam sterilized caudate nucleus tissue of PD patients by endpoint-titration.

Five minutes of steam sterilization reduced this titre by only 2.25 ± 0.15 decadic-logarithmic units, with an extension of the sterilization time to 90 minutes not causing additional inactivation.

CONCLUSIONS

Our findings reveal αSynPD species as disease-associated biological agents the seeding activity of which has a higher resistance to steam sterilization than that of prions. As long as health risks possibly emanating from iatrogenic transfers of PD-associated αSynPD seeds cannot be ruled out, the remarkable heat-resistance of these biological agents cautiously suggests additional physical or chemical cleaning and disinfection methods to thouroughly deplete or inactivate contaminations of seeding-active αSynPD aggregates when reprocessing medical devices.

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This document is intended to provide information to an international audience outside of the US.

VALIDATION OF A CLEANING VERIFICATION TEST FOR LUMENED MEDICAL DEVICES

PRESENTER
Kaumudi Kulkarni
Mary Ann Drosnock

Healthmark Ind - Fraser (United States)

AIM

Thorough cleaning processes are required before disinfection or sterilization because inorganic and organic materials that remain on the surfaces of instruments interfere with the effectiveness of these processes (CDC, 2008). Removal of protein soils and verification of this process is integral to successful terminal processing steps.
The aim of this study was to validate an easy-to-use, qualitative cleaning verification test to detect residual protein in channels of lumened medical devices after manual cleaning. There were three subset studies performed towards this: the coupon testing study to establish the limit of detection, channel testing study to determine extraction efficiency, and clinical testing to demonstrate the efficacy of this test in clinical use.

METHODS

To evaluate the Limit of Detection (LOD) of the product, PTFE coupons were inoculated with five known concentrations of BSA with three replicates per concentration. A recovery rate study was also performed for each concentration.
To assess the extraction efficacy, PTFE tubing of 150mm in length and 2.7mm in diameter was used to mimic an endoscope channel. The tubing was first washed with a non-enzymatic detergent, brushed, and rinsed with water for injection. The tubing was then inoculated with five known concentrations of BSA (with three replicates for each) and then dried. The tubing was then tested for proteins according to the manufacturer's instructions.
To demonstrate the efficacy of the test in clinical use, live endoscopes after clinical use and manual cleaning were sampled for bacteriological analysis, TOC, and protein analysis. In total 90 endoscopes were sampled: 30 gastroscopes, 30 bronchoscopes, and 30 colonoscopes.

RESULTS

The lowest tested protein concentration that showed a passing result was 1.3µg. Therefore, that was determined as the limit of detection for the test. For the extraction efficacy study, the test detected 5ug of proteins, which corresponds to 0.4 µg/cm2.
The third subset study is currently ongoing, and results are expected around July 2022.

CONCLUSIONS

The study utilized a thorough protocol and demonstrated a low limit of detection of the cleaning verification test. The test was sensitive at picking up proteins as low as 1.3µg. The extraction efficacy study demonstrated that the cleaning verification test being validated was indeed effective in detecting proteins in PTFE tubing that mimicked endoscope channels- and the detection limit was well below the action threshold of 3 µg/cm^2 specified in ISO 15883-5:2019. Results of the third subset study will be entered after the study is completed.
This study results demonstrate that this test method is a useful cleaning verification tool for sterile processing professionals to check for residual proteins in the channels of lumened devices after manual cleaning. Demonstrating adequate protein removal will help medical device reprocessing departments achieve manual cleaning and therefore set them up for success in disinfection or sterilization.

References / Acknowledgements
CDC Guideline for Disinfection and Sterilization in Healthcare Facilities (2008)

TO BORESCOPE OR NOT TO BORESCOPE

PRESENTER

Frank Daniels

Vcu Health Systems - Richmond (United States)

AIM

This abstract aims to inform organizations, groups, and people that borescope is necessary. People tend to trust the original equipment manufacturer (OEM) when they send flexible endoscopes to be repaired and believe a third-party cannot repair the device correctly. If a flexible endoscope is not repaired properly or has defects, then it can lead to patient harm or cause an outbreak.

METHODS

I have required a borescope to be used on all flexible endoscopes both upon arrival into the facility and when returning from being repaired. The flexible endoscopes are then evaluated to ensure there is no potential of harming patients or causing problems with reprocessing the medical device. This can range from a small scratch to a large obstruction within the flexible endoscope.

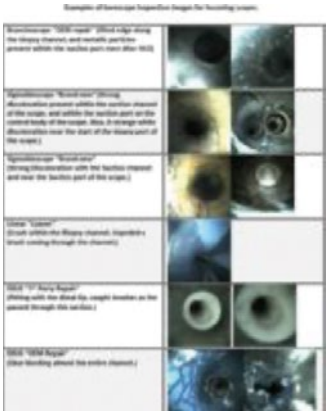
RESULTS

We had a total of thirty-six flexible endoscopes that were rejected in 2021. This consisted of eight new and twenty-eight repaired flexible endoscopes. Of the fixed scopes, eighteen came from the OEM, and ten came from a third-party repair vendor. This was a total of a twenty-three-percentage fail rate of overall flexible endoscopes that were either new to the facility or sent out for repair.

CONCLUSIONS

With the percentages being so high, more organizations, groups, and people need to hold not just the third-party repair companies but the OEM manufacturers accountable. We currently have an agreement with a third-party repair facility and an OEM that all scopes sent to my facility must have a borescope to check the internal channels before shipping the flexible scopes back to us. With new technology available, we need to utilize it to prevent guessing at the quality of work being sent back to us to be used on patients. Any of the thirty-six flexible endoscopes that were rejected could have harmed a patient. How many have been missed in the past before we started using a borescope?

Examples of damaged endoscopes



References / Acknowledgements

doi.org/10.1055/a-1591-0258, doi.org/10.1055/a-1512-2813, doi.org/10.1016/j.ajic.2016.06.029, doi.org/10.1016/j.gie.2018.04.2366, doi.org/10.1016/j.gie.2018.07.005

CLEANING OF ROBOTIC INSTRUMENTS: CAN WE REDUCE THE WORK LOAD IN THE CSSD AND IMPROVE PATIENT SAFETY?

PRESENTER
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CO-AUTHORS
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Smp Gmbh Pruefen Validieren Forschen - Tuebingen (Germany)

INTRODUCTION

In the late 90ies of the of the last century the first robotic system was introduced into the operation room by Intuitive Inc. The delicate devices are still challenging, when we are talking about cleaning. Meanwhile most manufacturers of washer-disinfectors have validated processes and specific load carriers for the devices of the pioneer in robotic surgery. In the meanwhile, competitors with new robotic systems show up in this specific market.
Cleaning processes in more than 15 different washer-disinfectors of different brands were released by Intuitive after extensive testing in our laboratory. Some of these processes have been tested in combination with automated pre-cleaning.
Since 2016 we have evaluated around 700 clinically used robotic devices from Intuitive for remaining proteins by an extraction procedure. In addition, devices at end of live were destroyed for extraction and inspected visually.

AIM

In the last few years robotic devices (6 types) from 5 different manufacturers have been examined by SMP for their cleanability. All of them need specific processes and most of them extensive manual pre-cleaning.
One approach to reduce the work load in the CSSD and improve the quality of cleaning at the same time is to combine an automated pre-cleaning process with a cycle for standard surgical devices in a washer-disinfector. Ideally a universal load carrier or the rack for MIS-instruments should be used instead of a specific load carrier for robotic device.
Developments are focused on automated pre-cleaning, optimization of the process parameters and improving the design of the robotic devices with respect to cleanability.

METHODS

Laboratory tests to evaluate the cleanability of robotic instruments in different washer-disinfectors using different cleaning detergents were performed by radioactive labelling of test soils (to localize critical positions of the device designs) and detection of residual proteins and hemoglobin after extraction.

RESULTS

The outcome of the protein tests on clinically used devices shows that robotic instruments can be safely reprocessed. Around 95% of the instruments evaluated at SMP had a level of less than 100 µg of residual protein. The average was 35 µg of protein, much lower than the acceptance level of ISO 15883-5.
Laboratory tests showed that automated pre-cleaning with an ultrasonic bath can reduce the manual pre-cleaning time as well as the process time of the washer-disinfector.

CONCLUSIONS

The new developments on ultrasonic baths, washer-disinfectors and improvements of the device designs will lead to less work and time intensive processes and improved process safety. Integration into existing structure and processes of CSSDs will become easier.

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NEW INSIGHTS INTO CHEMICAL PASSIVATION OF STAINLESS SURGICAL STEEL: CORROSION PREVENTION AND BEYOND

PRESENTER

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[2] *Empa. Swiss Federal Institute For Material Science And Technology. Dpt. 202 – Laboratory For Joining Technologies And Corrosion - Dübendorf (Switzerland)*

[3] *Empa, Swiss Federal Institute For Material Science And Technology, Dpt. 404 – Laboratory For Biointerfaces - Dübendorf (Switzerland)*

AIM

The aim of this work was to generate new insights on surface oxide modification of stainless steel through chemical passivation with respect to passive oxide layer thickness, corrosion resistance and surface properties.

METHODS

A novel development of the method called HAXPES *(Hard X-ray Photoelectron Spectroscopy)* allowed us to analyze the top 20 nm of stainless steel coupons treated with a phosphoric/nitric acid-based solution[1] or a citric acid-based solution[2] in comparison to untreated coupons. Ongoing experiments include classical electrochemical characterization, water contact angle measurements, wet chemical corrosion tests, as well as assessment of the adhesion of protein and microorganisms to the surfaces.

RESULTS

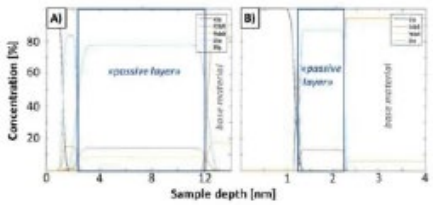
Background: Corrosion damage to surgical instruments is associated with high costs. Characterized by a high chromium content, stainless steel forms a chromium oxide-rich layer on its surface. The formation of this "passive layer" occurs spontaneously, but can be optimized and its protective nature enhanced by treatment with chemicals. The passive oxide layer is assumed to act as a kinetic barrier to atmospheric oxygen and to inhibit the diffusion of iron cations to the instrument surface, thereby preventing the detrimental oxidation of large amount of metallic iron towards the familiar brownish iron oxides («rust»). Daily use conditions further promote corrosion: Halide ions (Cl- [chloride], I- [iodide], Br- [bromide]) from blood, saline solution or disinfectants attack the passive layer, in addition to mechanical damage, or steam sterilization. Classically, the Cr_{ox}:Fe_{ox} (chromium oxide: iron oxide) ratio on the steel surface, which can be estimated by X-ray Photoelectron Spectroscopy (XPS), is referred to as quality criterion of a passivation process. However, XPS is limited by the penetration depth of the X-ray source allowing only for examination of the approximately top 5 nm of the surface.

Results: The different chemical passivation methods resulted in significantly different compositions of passive layers. The treatment with the phosphoric/nitric acid-based solution[1] on 1.4021 steel resulted in a 5-fold thicker passive layer that exhibited better tolerance to aging under atmospheric conditions than the treatment with the citric acid-based solution[2]. First data indicate prolonged hydrophobic properties of coupons treated with the phosphoric/nitric acid-based solution[1].

CONCLUSIONS

Chemical passivation can modify the surface of stainless steel, making a significant contribution to maintaining the value of the instrumentation and likely facilitates reprocessing. Passivation of stainless steel surfaces may not only improve corrosion resistance, it may also affect the adhesion of contaminants and microorganisms.

Calculated passive oxide layer of treated steel.



References / Acknowledgements

[1] *deconex® 34 GR*

[2] *deconex® ORGANACID*

METHODS FOR THE DETERMINATION OF PROCESS CHEMICAL RESIDUES AFTER REPROCESSING MEDICAL DEVICES

PRESENTER

Matthias Tschoerner

CO-AUTHORS

Georg Rohm

Stefanie Lohse

Chemische Fabrik Dr. Weigert Gmbh & Co. Kg - Hamburg (Germany)

AIM

With a proper reprocessing of medical devices only toxicologically acceptable residue of the used process chemicals may remain on the surfaces after completion of the cleaning and disinfection which preclude any risk to patients, users and third parties.
The manufacturer of the process chemicals must define tolerable limits and provide appropriate analysis methods for determining residues that make it possible to detect the presence of process chemicals below these limits.
The limit values of the process chemicals to be observed are derived either from toxicological properties and from the intended use or may result from a biological assessment of the remaining residues in accordance with the EN ISO 10993 series of standards.
Due to the process chemistry, different analytical methods are used. Often sum-parameters such as the determination of the electrolytic conductivity of the final rinse water or the determination of the total organic carbon content (TOC) have become established. These parameters are still accepted in accordance with the last amendment of Annex 15 of the EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use, Annex 15: Qualification and Validation]. However, they are quite unspecific and must therefore be evaluated in the context of acceptance criteria and risk analysis.
There are only a few publications about the residual process chemicals remaining on the medical devices after cleaning and disinfection, most dealing with chemical residues on endoscopes.
Medical devices such as surgical instruments, rigid and flexible endoscopes and implants often come in contact with surfactant-containing cleaning agents during reprocessing. Residues of surfactants are often difficult to detect and even more difficult to quantify.

METHODS

For the characterization and identification of nonionic surfactants as well as their quantification, liquid chromatographic methods with mass spectrometric detection (LCMS) were developed only in the recent past.
An LCMS method was developed by combining a wide variety of measurement techniques on a Tandem MS, which enables both the identification of the type of surfactant used and its quantification in the single-digit ppb range.
This method was applied to test specimen and real life instruments.
For this purpose, a washer disinfector (WD) was equipped with test specimens of different materials and subjected to multiple, automated cleaning processes (up to 500 cycles) in several test series. Common materials used in medical devices, such as austenitic steel, as well as thermoplastic and elastomeric plastics have been used for the specimens.

RESULTS

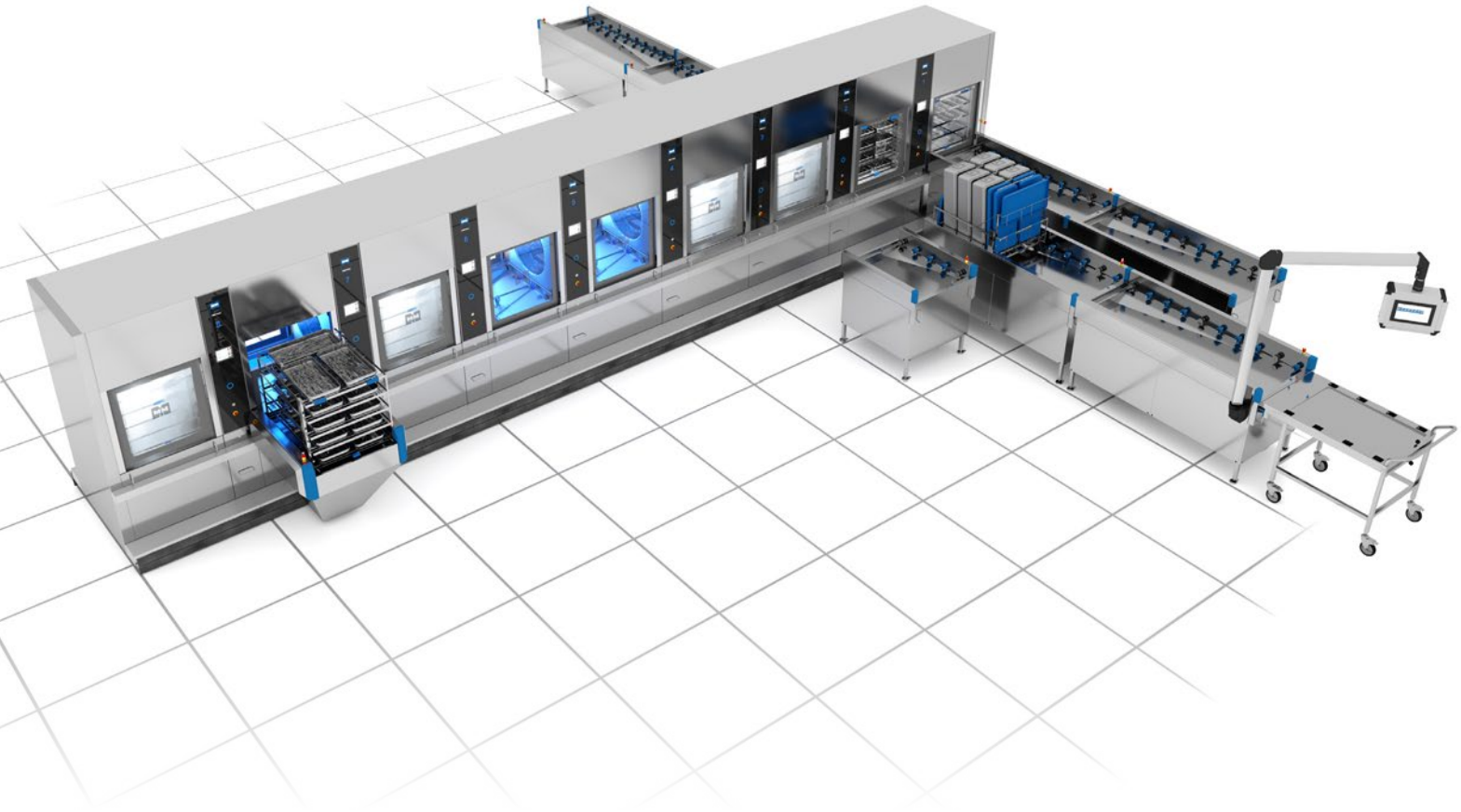
The analytical results of the tests on residues of nonionic surfactants obtained under the selected conditions were compared with the results of the biological evaluation (in vitro cytotoxic testing).

CONCLUSIONS

The data demonstrate that the limits for toxicologically acceptable residues are respected with proper reprocessing procedures. However, instruments from the field show some exceeding of the limits resulting from insufficient rinsing.
This method is a working tool to increase the safety when developing and validating reprocessing procedures.

Soluciones integrales para el reprocesamiento de material estéril

De la planificación a la realización: unidades de reprocesamiento para productos sanitarios de un solo proveedor.



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STATISTICAL EVALUATION OF PROTEIN LEVELS OF TEST OBJECTS AND REAL INSTRUMENTS AFTER CLEANING IN WASHER-DISINFECTORS: RESULTS FROM THE YEARS 2015 – 2022

PRESENTER

Karen Dr. Seekamp-Schnieder

CO-AUTHORS

Ludger Dr. Schnieder

Klaus Roth

Smp Gmbh Tübingen - Tübingen (Germany)

AIM

It is the aim to present detailed data on the validation and revalidation of cleaning processes in washer-disinfectors for the period from 2015 to 2022. Results from quantification of residual protein levels from approx. 500.000 test pieces and real used instruments from hospitals and dental offices mainly located in Germany will be shown. The results of test specimens and real instruments are compared with each other in terms of their meaningfullness. Developments observed over the investigation period are discussed and compared with previous results from 2013[2].

METHODS

Since the initial compilation of a German guideline for the validation and routine monitoring of automated cleaning and thermal disinfection processes for medical devices in 2005[1] contaminated reference test objects (Crile clamps contaminated with test soil according to standard operating procedures) are used to monitor and evaluate automated cleaning processes. In addition, real, in-use soiled instruments are used to provide a reference for practice-specific loading and for cleaning assessment of differently designed instruments. Residual amounts of proteins after cleaning were extracted from Crile clamps (performed in the laboratory) and real used instruments (performed on site) with 1% SDS-solution.
To extend the concept of using standardized test objects and real used instruments to the dental area a two-part test object for the evaluation of the interior and exterior cleaning of dental handpieces and contra-angles was developed and validated. Again, extraction of residual protein from the test objects was performed in the laboratory whereas the real used instruments are extracted on site by trained personnel.
Protein quantification was performed using two different assays in combination with a hemoglobin test to rule out false positive results.

RESULTS

Starting with a selection of results of single validations statistical evaluations of the protein values addressing the development over time and the comparison between test objects and real used instruments will be presented. Due to the large number of results a detailed discussion of trends and the effects of possibly changed acceptance values will be shown.

CONCLUSIONS

When the guidelines for the validation of mechanical processes were first published in 2005[1], an acceptance value of 100 µg residual protein per test object was specified.
After the publication of a comparative study of the residual protein levels on test objects and real instruments after cleaning in 2013[2], the acceptance value for successful cleaning was readjusted to ≤ 80 µg and published in the 4th edition of the guideline in 2014[1].
The validations carried out since 2015 have clearly shown that both the use of test objects and the sampling of real instruments are important in order to evaluate the cleaning performance of washer-disinfectors and to identify insufficient cleaning processes. The large number of results from validations presented here can be of help in the evaluation of existing or newly defined acceptance criteria.

References / Acknowledgements

[1] Central Sterilization 2017; Supplement 5th Edition and previous Editions

[2] Michels W. Central Sterilization 2013; 3: 212-215

CONTRIBUTING FACTORS ON DUODENOSCOPE REPROCESSING AND VERIFICATION OF INTERDEPENDENCIES IN CLINICAL SETTINGS

PRESENTER

Annette Rittich

Olympus Europa Se - Hamburg (Germany)

AIM

Between September 2018 and January 2021, a leading endoscope manufacturer had implemented a nation-wide program in France called "Evolution", to gain a deeper understanding of actual reprocessing practices and deviations from its reprocessing instructions for a certain type of duodenoscopes. The initiative based on a regulatory request and supposed to confirm the safety of the device in clinical use.

METHODS

Specially qualified technicians performed on-site visits to all endoscopy accounts that were using the specific duodenoscope. The status quo of staff training, reprocessing workflow and actual device condition were individually recorded. A dedicated and standardized digital tool provided immediate feedback on the importance of observed deviations from the manufacturers' reprocessing instructions.

After the visit, all facilities received an immediate feedback on the observations and were proposed short- to mid-term improvement measures.

RESULTS

In total, 182 hospitals were visited in the context of the nation-wide study. A total of 31% revealed medium to important non-conformities.

During the observation of the daily reprocessing workflow, deviations were noted on 34 out of 135 essential steps. Over 50% of these deviations referred to the reprocessing of the distal end and i.e. the elevator lever, which due to its complex design requires specific attention.

When reviewing the actual trainings status of the reprocessing staff, only 35% were in fact trained by the legal manufacturer of the duodenoscope. 59% of all reprocessing technicians had undergone internal training measures or peer-to-peer qualification, while 6% of the staff had not received any training at all.

Correlating the reprocessing workflow deviations with staff qualification levels, it could be determined that reprocessing technicians exclusively trained by the legal manufacturer performed evidently better than staff with only internal training. Untrained staff displayed the most important deviation levels.

A close inspection of the duodenoscope condition used on site generally revealed only few non-conformities that would require the intervention of a qualified service center. If damages were observed, they mostly related to the distal end.

Cross-linking damage occurrence with staff qualification levels revealed that device damages increased significantly when staff had not been trained at all.

As counteractions, all visited facilities received refresher trainings focusing on the observed areas of deviation during the on-site visit. Visual support materials were made available to all facilities, as well as device inspection check lists. The latter specifically address the periodic inspection by hospital internal biomedical engineers, which is recommended in addition to the routine function check before each patient procedure.

CONCLUSIONS

The nation-wide study confirmed with real world evidences the importance and especially the interdependence of the most crucial contributors to successful duodenoscope reprocessing: staff qualification, adherence to the reprocessing instructions and device condition.

Hands-on training and visual support materials provide important qualification and guidance to reprocessing staff in day-to-day tasks, allowing for the safe reprocessing of complex duodenoscopes and making an important contribution in the prevention of patient infections.

CONFERENCE 13 QUALITY IN ENDOSCOPE REPROCESSING

ENDOSCOPE REPROCESSING: RETROSPECTIVE ANALYSIS OF 90 311 SAMPLES

PRESENTER

Lionel Pineau

Eurofins Biotech Germande

AIM

The contamination level of ready to use endoscopes published in the literature, varies from 0.4% to 49.0 %. Unfortunately, the comparison and the interpretation of these results is quite impossible regarding the limited number of samples and sites included and the differences observed between sampling, culturing methods and interpretation criteria. The objective of this retrospective study was to analyse the results of 90 311 endoscopes samples collected between 2004 and 2021 in 490 private or public hospitals in France.

METHODS

The sampling and culturing methods were based upon the French guidelines regarding microbiological monitoring of endoscope and traceability in endoscopy published in 2007 and the recommendations published in 2018 dedicated to duodenoscope reprocessing and sampling.

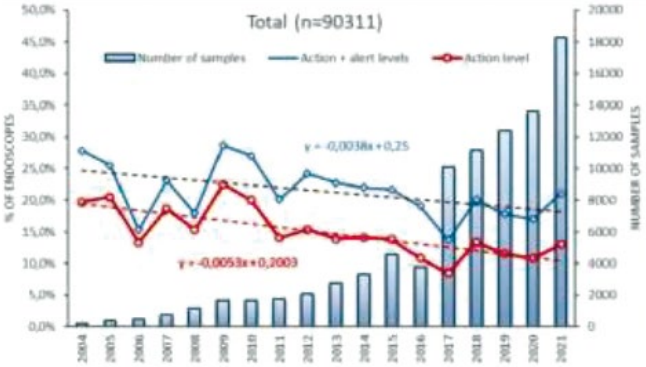
RESULTS

90 311 endoscopes were sampled between 2004 and 2021 in 490 private or public health facilities all located in France.Through the full test period, the mean ratio of endoscopes at the action level is 12.6% (19.5% including alert level). 23.0% of the endoscopy units present a ratio of compliant endoscopes (target level) lower or equal to 70.0%.
The overall microbial quality of gastroscopes, duodenoscopes and colonoscopes is improving year by year whereas a downward trend is observed for ultrasound endoscopes and bronchoscopes. In 2021, following French guidelines, 13.0% of the endoscopes should be quarantine and 8.1% are at the alert level, meaning that the contamination level of 21.1% of the endoscopes is exceeding what was defined as a maximum acceptable value.

CONCLUSIONS

This study demonstrates that additional efforts, including implementation of microbial surveillance strategies using a standardized sampling method and periodic observational audits, must be made to improve the overall microbiological quality of endoscopes and reduce the risk associated with their use.

Evolution of the ratio of non-compliant endoscopes



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ASSESSMENT OF NOVEL ANTIMICROBIAL MATERIALS TO PREVENT BIOFILM FORMATION IN CRITICAL AND SEMI-CRITICAL MEDICAL DEVICES

PRESENTER

William Leiva[1]

CO-AUTHORS

Paulo Laranjeira[2]

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[2] *Orion - Boca Raton (États-Unis)*

AIM

This project, is pursuing to gather evidence regarding the use of PLA in medical devices, document its benefits and explore application using additive manufacturing or conventional or vertical injection molding process. The primary aim of this research is to assess the effectiveness of PLA polymer infused with copper nanoparticles, to reduce and/or prevent bacterial growth of microorganisms and the formation of biofilms and explore potential applications on endoscopic devices.

METHODS

The primary aim of this research is to assess the effectiveness of PLA polymer in conjunction with copper, to reduce or prevent bacterial growth of microorganisms of concern and the formation of biofilms. The research includes: Literature Review including the assessment of current testing references and the microorganisms of interest.
Assessment of material performance and its antimicrobial effectiveness using microorganisms of interest under a standardized testing protocol developed based on ISO 22196 and conducted on third-party laboratories.
Draft of article to be submitted to peer review journals.

RESULTS

The assessment of potential testing protocols points towards the used of standardized testing based on ISO 22196:2011- Measurement of antibacterial activity on plastic surfaces. From a literature review perspective, evidence shows previous efforts to develop products for aerospace application to benefit from the antimicrobial properties of the PLA polymer, including reduction of microbiological activities over the surface of the novel material when exposed to multiple microorganisms, including microorganisms of concern. Literature also points towards multiple applications, most of which are based on non-critical and semi-critical devices. The PLA substrate prevents microbiological growth in the tested coupons. These tests were conducted on a third-party laboratory with ISO 17025 Accreditation based on the testing procedures described on ISO 22196. The results are based on non-sterile coupons inoculated with Klebsiella pneumoniae, Pseudomonas aeruginosa, Escherichia coli and Salmonella enteritidis.

CONCLUSIONS

Available literature points towards an effective microbiological activity reduction attributable to the PLA polymer. This built the case to expand the testing to microorganisms of interest, particularly those related to infections after endoscopic procedures. The evidence gathered during this research, point towards the direction of a material with rather interesting properties for use in general medical devices development and specifically flexible endoscope applications. The log reduction attributable to the material shows promising results with current microorganisms which will be expanded to the microorganisms of interest for endoscopic applications to take place in the latter part of August 2022. After the coupons development and testing; and once results are available and disclosed; future steps of the research -subject to funding- will encompass the testing of mechanical properties for custom made designs, including alterations of the product surface, antimicrobial performance over time, discoloration or changes on material stiffness; to better assess replacement either with new or upcycled products. Future testing should also include the impact of reprocessing using conventional decontamination and sterilization technologies on the material properties. All of these, based on different manufacturing technologies including conventional injection and or additive manufacturing.

References / Acknowledgements

This research have been partiatially funded with a AAMI Foundation Kilmer Grant.

IMPLEMENTING AN EVIDENCE BASED PARAMETRIC LOAD RELEASE FOR STEAM STERILISATION IN PRACTICE

PRESENTER

Anke Van Rosmalen

CO-AUTHORS

Willemijn Zwinkels

Franciscus Gasthuis En Vlietland - Rotterdam (Netherlands)

AIM

To implement an evidence based parametric load release for steam sterilisation processes. With the additional requirements that the method has to be more sustainable than current methods and reduces the use of resources.

METHODS

Based on the findings of a literature study in combination with consensus based standards a set of requirements for steam sterilisation conditions was identified. In the field a search for methods that could be applied was performed. A device was identified, studied and implemented.

RESULTS

The literature study demonstrated determining the steam composition with pressure and temperature measurements is not possible. This is written out in a document of the SVN (Dutch Sterilisation association [1]. The biological and chemical alternatives were all not more sustainable as the current method applied in our hospital, because it produces more waste, uses (conditioned) storage and transportation.

For the search for a devices the physical criteria for steam sterilisation had to be specified. Based on the literature [2] and the consensus based European standard [3,4] the criteria to monitor are determined. For example for a 134 ° C steam sterilisation process the monitoring criteria are:

Throughout the chamber and load	134 degrees	≤	T	≤ 137 degrees
NCG's in the free space of the chamber		NCG's	≤	$3,5\ ^{V_{NCGs}}/_{V_{100ml\ condense}}$
Sterilisation time (holding phase)		t	≥	180s

In which T is the temperature, NCGs the Non Condensing Gases, and, t the time. Additionally, the load has to be dry after the process.

The NCG-sensor (Figure 1) was the elected device that can monitor the physical parameter temperature, NCGs and the time in very process. The NCG sensor is installed on a validation port of the steriliser and does not influence the process. To release the load an Every Load Monitoring protocol is available within 30 s after each steam sterilisation process.

It is important to mention that the 7 steam sterilisers complied with the standards [3,4] during the Performance Qualification.

A return of investment is made and demonstrated a return of Investment (ROI) of less than 2 year. By using the numeric data of the NCG-sensor trend analyses can be performed.

CONCLUSIONS

With the use of the NCG-sensors in our hospital we

- Implemented an evidence based load release for steam sterilisation
- Ensure a better sterilisation process then before
- Are more sustainable, because less use of energy, water, indicator material and storage then before
- Established a cost reduction.

NCG sensor

CONFERENCE 16 MONITORING THE EFFECTIVNESS OF STERILIZATION

EFFECTIVENESS OF DISINFECTION AND STERILIZATION IN LAPAROSCOPES AND ARTHROSCOPES AND THEIR RISK OF INFECTION: A SYSTEMATIC REVIEW

PRESENTER

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CO-AUTHORS

Liliana Elizabeth Rodríguez Salgado [1]

Gina Lorena Hincapié [2]

José Bareño [3]

[1] *Asp Advanced Sterilization Products Colombia - Bogota (Colombia)*

[2] *Asp Advanced Sterilization Products Colombia - Toronto (Canada)*

[3] *Universidad Ces - Medellín (Colombia)*

AIM

To determine the effectiveness of high-level disinfection and sterilization in laparoscopes and arthroscopes used in minimally invasive surgery, identifying their relationship with the development of infections associated with their use.

METHODS

Systematic review of the literature that identified articles published from 1978 to July 27, 2021, in English, French, Portuguese and Spanish, taking into account the following inclusion criteria: primary studies of minimally invasive surgical procedures by laparoscopy or arthroscopy, high-level disinfection, sterilization and health care-associated infections. Three investigators searched 14 databases, with standardized terms DeSC, MeSH, ENTREE and free terms, in the following search engines, PubMed, EMBASE, CENTRAL, ScienceDirect, BVS, SciELO, LILACS, Google Scholar, Scopus, Web of Science, https://clinicaltrials.gov/, ICTRP, Grey Literature and OpenGray.

RESULTS

We identified 833 records from 11 databases, removed 178 duplicates, and included six primary articles, two of which were in favor of sterilization, one in favor of disinfection, two unbiased, and one related to single-use medical devices.

CONCLUSIONS

It is evident that there is a lack of studies and clinical trials comparing the effectiveness of reprocessing methods of laparoscopes and arthroscopes; additionally, it is necessary to develop more research in the area, involving a rigorous methodology and participation of different areas of knowledge.

References / Acknowledgements

Huezo CM, DeSTEFANO F, Rubin GL, Ory HW. Obstet Gynecol. 1983;61(5):598-602. Stearns CM, Stearns III HC, Jablonski J, Kirchhoff K, Keres K, Seybert D. Orthop Nurs. 1983;2(2):38-44. Rutala WA, Clontz EP, Weber DJ, Hoffmann KK. Infect Control Hosp Epidemiol. 1991;12(5):282-8. Ayliffe G, Babb J, Bradley C. J Hosp Infect. 1992;22(4):265-9. Muscarella LF.Infect Control Hosp Epidemiol. 1996;17(3):183-7. Ulualp KM, Hamzaoglu I, Ulgen SK, Sahin DA, Saribas S, Ozturk R, et al. Surg Laparosc Endosc Percutan Tech. 2000;10(2):59-62.

MONITORING STEAM PENETRATION IN CHANNELED INSTRUMENTS: AN EVIDENCE-BASED WORST-CASE FOR PRACTICAL SITUATIONS

PRESENTER

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AIM

Steam sterilization of channeled medical devices requires steam penetration into narrow channels. However, a quantitative characterization of this phenomenon in practical situations is lacking. This study evaluates the effect of load, loading pattern, and wrapping system on steam penetration into channels. We tested the hypothesis that a 70 cm tube with one closed end could be representative of the worst case for steam penetration in wrapped channeled instruments in practical conditions.

METHODS

A validated sterilization process was run in a sterilizer equipped with infrared sensors for the measurement of water vapor fraction (WVF). WVF values collected at the closed end of an unwrapped 70 cm reference tube were compared to those obtained at the closed end of wrapped 50 cm test tubes, representative for channeled devices in the clinical practice. The open ends of the test tubes were placed inside packs, testing the effects of different combinations of wrappings, load amounts, and pack positions. The worst case for steam penetration was experimentally defined as the condition showing the lowest WVF value during the exposure phase.

RESULTS

WVF values at the closed end of 50 cm long tubes were affected by load amount, wrapping, and pack position. Steam penetration was higher for heavier loads in rigid containers, but lower for heavier loads in soft wrappings (pouch, non-woven fabric, and crepe). In all the tested combinations of load/wrappings related to the clinical practice the 70 cm reference tube displayed lower WVF values than the wrapped 50 cm test tubes, indicating worse steam penetration in the reference than test tubes.

CONCLUSIONS

Our findings provide experimental evidence that a 70 cm is the worst case in all practical combinations of load and wrapping encountered in the field. The 70 cm tube is a representative for a wrapped 50 cm channel with one end closed and for a wrapped 100 cm channel with both ends open. A measuring system integrating the WVF sensor on a 70 cm tube may provide a physics-based, quantitative steam penetration test for real-time monitoring of the steam sterilization process of channeled instruments.

REFERENCES

Tessarolo, F et al. Front Med Technol 2020, 2, 566143, doi:10.3389/fmedt.2020.566143.

INDIVIDUAL SURGICAL INSTRUMENT TRACEABILITY: IN LINE WITH THE EUROPEAN REGULATION MDR 2017/745/EU

PRESENTER

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AIM

The new European regulation MDR 2017/745/EU aims to increase quality, performance, data transparency and medical devices securing. It is based in part on deeper CE marking files, notified bodies revaluation and higher traceability levels. In the same way, French "Bonnes Pratiques de Pharmacie Hospitalière" try to improve quality management in sterilization units. Risk management follows the same goal. Furthermore, limited budget incites to take a closer look on the path of expensive or fragile medical devices. Operating room staff shortage results in tasks and skills transfer to sterilization staff. Individual instruments traceability could answer these requirements.

METHODS

When available, Unique Device Identification (UDI) as data matrix given by the supplier is used. If not, surgical devices are engraved in sterilization unit with Polybox® laser engraver. Marking is a unique data matrix for each surgical device. It allows an individual traceability. Marked instruments are read and identified at the stage of packaging. Laser marker can both engrave instruments and containers.

RESULTS

In 2020, instruments to be engraved were estimated at 45 000. Marking activity began in December 2020. In 2020, 108 instruments have been engraved, 15 600 in 2021 and 7 070 between January and May 2022. For containers, 32 have been marked in 2020, 246 in 2021, and 109 on the first half of 2022. Marking enables instruments monitoring, and provides statistics about specialties. Marked instruments loss was estimated at about 10% of the total number of marked instruments. Engraving allows an easier tracking when an instrument has a limited approved number of sterilization cycles. Sterilization staff training program about packaging and instruments recognition is shorter. It makes the skills transfer easier. However, there is a long training program for engraver using. Determination of the appropriate program for a support material takes time and is essential for the mark durability. Indeed, some data matrix codes were less and less readable over time, and needed new engraving. Supplier's propriety ancillaries cannot be engraved. Two years of work are yet necessary to engrave the instrument inventory, and to have an exhaustive individual traceability.

CONCLUSIONS

Instruments marking is a time-consuming activity, which needs investments and consistency. It has shown a regular mixing of instruments between different surgery containers used for an operation, and a loss of a lot of instruments. It allows an exhaustive traceability, an establishment of a system for repair broken instruments and replace the permanently broken instruments. It also allows a computerize planning for containers upkeep. It highlights the pool costs of needed surgical instruments, and permits an optimized risk management. Individual identification is an essential prerequisite for a future automation of packaging steps. It may be coupled, for example, to a containers following based on a radio identification system (RFID).

IMPROVEMENT OF MANAGEMENT EFFICIENCY BY VERIFYING THE EXPIRATION DATE OF STERILIZED PRODUCTS

PRESENTER

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AIM

The expiration date of sterilized products should be set in consideration of packaging materials and storage environment, but since its opening in 2003, it has been applied without verification of the expiration date.
Until now, the quality of the storage and packaging materials of the sterilized products has been improved, and it is necessary to reset the expiration date of the sterilized products accordingly. In addition, the purpose of the study is to reduce the amount of re-sterilization due to a short shelf life.

METHODS

- 19 places with a large amount of sterilized products and weak storage environment were selected, and temperature, humidity and environment ware checked.
- The 7.5cm long cotton swab was sterilized in Crepe paper, non-woven wraps, Rigid Sterilization Container, Paper-plastic pouch, Tyvek.
- Crepe paper, non-woven wraps, and Rigid Sterilization Container, were cultured 8 times in total, 6 to 20 weeks (interval: 2 weeks), after sterilization.
- Paper-plastic pouch and Tyvek, were cultured for a total of 12 times, 26 to 48 weeks (interval:2 weeks), after sterilization.
- Bacterial culture was Inoculated with Thioglycollate broth, incubated at 35°C for 7 days, and then inoculated with BAP and MAC, incubated at 35°C for 2 days in CO2.
- The amount of re-sterilization was confirmed.

RESULTS

- Bacillus bacteria were detected on Crepe paper in two departments at 18 weeks out of a total of 20 weeks, so the expiration date of the Crepe paper, non-woven wraps, and Rigid Sterilization Container was extended from 4 weeks to 12 weeks
- Paenibacillus species bacteria were detected on Tyvek in one department at 38 weeks out of a total of 48 weeks, so the expiration date of the Paper-plastic pouch and Tyvek was extended from 24 weeks to 32 weeks
- An average of 204 cases of re-sterilization per month decreased by 82.8% to 35.
- The average monthly cost of re-sterilization decreased from $2656 to $498.
- In terms of Satisfaction with the expiration date management work for operating room nurses, 67% was dissatisfied before improvement and 77% satisfied after improvement.

CONCLUSIONS

Through this study, the expiration date of the existing 4 weeks was extended to 12 weeks and 24 weeks to 32 weeks, and the re-sterilization amount was reduced by 82.8%.
The expiration date of sterile products depends on the packaging material and storage environment. Packaging materials are continuously being developed and quality is also improving. User's awareness of the the storage and management of sterile products is also improving, and most of the sterilized products storage centers in the hospital consist of closed cabinet, and the standard environment is relatively well maintained. Accordingly, through periodic follow-up studies, it is suggested to switch to the event-related expiration date management rather than time-related the expiration date.

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MODELING A TOOL FOR PLANNING A NEW CSSD

PRESENTER

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AIM

In Belgium, the CHU UCL NAMUR (university hospital) and the Clinique Saint-Luc in Bouge (regional hospital) will carry out, within 2 years, a shared CSSD for 3 sites or location in one place outside the hospitals. This new CSSD is called CARE-NAM.

The project managers wanted to call on expertise of advisers specialized in data management, process simulation or other innovative expertise (AI, etc.) that could optimize the multiple flows linked to this outsourced sterilization process. The idea, for our institutions, is to integrate a dimension of expertise in industrial "supply chain" in a hospital project.

The objective of this work was, in a first phase called STRATEGIC, to size CSSD (SIZING) to best meet the current realities of hospitals. To do this, data is available (i.e., OR schedule).

The aim is to model the operation of our future outsourced CSSD (3 hospitals) based on real activity data. The objective is to be able to define the most efficient model by finding a balance between the number of people, the schedules, and the quantity of equipment (washers, steam sterilizers, ...) to be planned. The result is a decision support tool that, by changing different variables, would allow to analyze different scenarios to choose the most efficient one. For example, this tool should be able to define the best time to collect soiled medical devices for transport to the CSSD.

METHODS

The parameterization of this tool will integrate data such as surgical activity, equipment cycle times or staff handling times at each stage of the process and will take care variables such as the number of people or equipment or the arrival times of the medical devices to be treated

RESULTS

A simulator made available to decision-makers that allows them, by modifying certain variables, to obtain a projection of material and human resource requirements.

CONCLUSIONS

Such a tool requires a long period of parametrization, after this period, it is a real asset for the dimensioning before the construction of the new CSSD. This makes it possible to objectify the choices made.

CONTAMINATION AND SURFACE DAMAGE ON REPROCESSED ROBOTIC SYSTEM SURGICAL INSTRUMENTS IN CLINICAL USE

PRESENTER

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AIM

To assess the cleanliness and surface condition of robotic system surgical instruments (RSSI) in clinical use.

METHODS

RSSI (da Vinci Surgical System; Intuitive Surgical) (n = 40 instruments - joint and tool) in clinical use in a large Sydney hospital, were collected after 10 uses and after reprocessing. RSSI collected included monopolar curved scissors, mega suturecut needle driver, large needle driver, cadiere forceps, fenestrated biopolar forceps, long biopolar grasper, prograsp forceps, permanent cautery hook, stapler 45, and maryland biopolar forceps. RSSI were reprocessed by manual followed by automated cleaning and steam sterilization. The joint and tool parts of the instruments were separated using a rotary tool, and subject to optical microscopy (Stereomicroscope System SZX16, Olympus). Samples showing a large amount of debris by optical microscopy were subjected to either Scanning Electron Microscopy (SEM), determination of protein contamination (Pierce BCA Protein Assay, Themofisher) or determination of level of corrosion using Potassium ferricyanide III (Sigma).

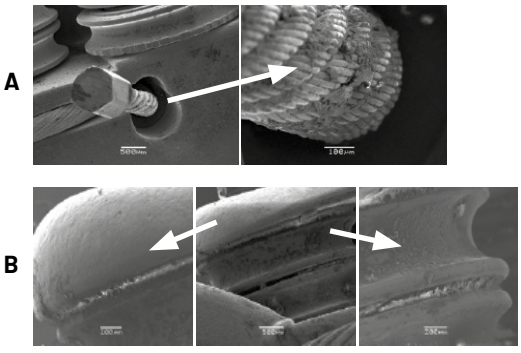
RESULTS

Debris was detected on all instruments (n = 7, joint or tool) subjected to SEM (Figure 1). Similarly, all the joints (n = 16) and tools (n = 10) tested were contaminated with residual protein, averaging 33 µg/cm^2 (range from 6 µg/cm^2 to 55 µg/cm^2). The area of the distal end of Maryland Bipolar Forceps has been estimated to be 27cm^2, and is representative of the typical type of construction of robotic instrument. Corrosion was verified on the outer surface of 26% of tools (n = 06/23) and in three of the 18 joints tested.

CONCLUSIONS

The small-sized and complex-design RSSI (joint and tool) were found to be contaminated with organic matter (protein) and to have surface damage (corrosion) immediately after 10 uses and subsequent reprocessing. An excessive amount protein was detected on reprocessed instruments including within the joints or on the tools. The average protein load was 33 µg/cm^2, which is more than 10-fold higher than the current recommended "alert level" of ≥ 3 µg/cm^2, and 5-fold than "action level" of ≥ 6.4 µg/cm^2. The benefits of performing robotic-assisted minimally invasive surgery must include a safe surgical instrument, that is not only sterile, but is without surface damage or contaminated with protein, which may lead to adverse effects to the patient. Therefore, the findings of this study point to the need for reassessing the reprocessing and reuse recommendation of these difficult-to-clean RSSI (small and inaccessible to brush areas), and for considering their provision as single-use and sterile instruments.

Figure 1



Scanning electron microscopy images of robotic system surgical instruments in clinical use after reprocessing. A - Debris on the wire of a surgical instrument joint. B – Debris on the pulley of a surgical instrument joint.

TIME IS RUNNING OUT, THE IMPORTANCE OF TIME AND ENVIRONMENTAL CONDITIONS ON CONTAMINATED INSTRUMENTATION

PRESENTER

Terra. Kremer

Johnson & Johnson - Raritan (États-Unis)

AIM

Within a healthcare setting there may be reprocessing delays that prevent customers from processing devices within the specified time outlined within the instructions for use. It has been suggested in the literature and within industry standards that proteins may undergo a chemical change when they are exposed to heat or experience prolonged drying times under ambient conditions. However, little experimental data is available in the literature to document this change or how to address for cleaning efficacy. This presentation will show the effects of time and environmental conditions on contaminated instrumentation from the point-of-use until the decontamination process begins based on recent research findings.

METHODS

In 2021/2022, research was conducted on the solubility of dried soil on reusable medical devices and the chemical changes of the proteins most prevalent in blood: mucin, lysozyme and albumin. Research methods include gravimetric and gel permeation chromatography (GPC) with a multi-angle light scattering detector (LENS3).

RESULTS

This cutting-edge investigation supports the scientific justification for point-of-use treatment and provides guidance for environmental conditions and time constraints when transporting soiled surgical instrumentation. Study results demonstrate that soil drying after a period of 8 hours changes the solubility of the soil complex. After an 8-hour dry, the solubility decreases in water, and a significant change occurs after 72 hours. Temperature will also contribute the chemical changes in protein. Although there was no significant difference between 4°C and 22°C, temperatures greater than 22°C demonstrated a decrease in soil solubility in water. An increase in humidity prevented the soil from completely drying and prevented the chemical changes effecting solubility to occur. Using a GPC analysis proved that some proteins like albumin coagulate while other like mucin and lysozyme denature. When water evaporates from this protein mixture the resulting chemical bonds increase the molecular weight resulting in the proteins becoming less soluble and therefore more difficult to remove. Further investigation was conducted to understand the effect of exposing dried soil to cleaning agents in an attempt to reverse the chemical changes. The dried soil was exposed to a variety of cleaning chemistries. Only alkaline cleaning agents were effective at reversing the chemical changes after a 60-minute soak and resulting in soil retention statistically similar to samples dried less than 8 hours.

CONCLUSIONS

Although it is hinted in industry standards that drying can change the chemical composition of the soil, there is a gap in the literature to fully understand the change in the protein chemistry during the drying time. In this presentation the authors will present findings from an experimental design to characterize the change to the proteins in blood soil. This important research will provide manufacturers the needed information to support the cleaning process within Sterile Processing to ensure patient safety even in unintended situations where cleaning is delayed.

References / Acknowledgements

Sue Klacik / HSPA

INVESTIGATION OF THE RELEASE OF PARTICLES DURING PHACOEMULSIFICATION PROCEDURES

PRESENTER

Sulisti Holmes

Dr - Edinburgh (United Kingdom)

AIM

- To investigate the sources of particle contaminants detected during phacoemulsification procedures;
- To prevent the release of particles to patient eye, that may cause post-operative infection such as endophthalmitis or toxic anterior segment syndrome[1].

METHODS

Particles were recovered by the surgeons during surgery in 3 hospitals. Particles were stored in a sterile plastic bottle containing Sterile Water for Injection prior to analysis. Initially, optical microscopy (10 - 100x magnification) was used to determine the colour and shape of the particles. The particles were analysed using Fourier Transform Infrared (FT-IR) spectroscopy over the range 4000 – 650 cm^{-1}. The particles spectra were compared with those from a range of reference materials such as brush, packaging and gowning material and all components in the consumable pack etc.

RESULTS

The colour and appearance of particles vary including opaque, white mass, clear fibres, dark and green fibres. The initial FT-IR analysis possessed signals suggesting the presence of acrylates, cellulose, polypeptide, polycarbonate, inorganic compounds and/or polyethylene polymer. The spectra were matched with those of protein, packaging, gowning materials, gallipot, saline as well as components in the sterile consumable pack. In conjunction with the manufacturer, a range of initiatives were employed to review and improve decontamination processes, environmental controls, and preserve the integrity and quality of sterile consumables.

CONCLUSIONS

Based on local surveillance data, there was no evidence of these incidents causing infection and/or patient harm. Due diligence of the surgeons ensured that particles were removed as soon as detected. However, the incidents have caused patient cancellation and delay in surgery which would affect the overall patient experience. After receiving 38 reports of particles found in the eye during or after surgery in the United Kingdom (UK) between 2017 and 2020, the UK Competent Authority issued safety information to minimise the risks of improper phacohandpieces cleaning[1]. The design of phaco handpieces presents challenges to the cleaning and sterilization process. The identification of polypeptides, the chain of building blocks of proteins, indicated the ineffectiveness of decontamination processes. However, other factors such as environmental conditions, where are they exposed to, and the integrity and quality of consumables should not be ignored. Before use, a sterile phaco handpiece is connected to the phacoemulsification machine using sterile consumables. A sterile wrench is used to tighten and untighten the needles.

References / Acknowledgements

[1] *DSI/2021/009. Handpieces used in the phacoemulsification technique of cataract removal: need for careful cleaning, Medicines & Healthcare products Regulatory Agency, 24 November 2021*

SUSTAINABLE DEVELOPMENT IN STERILIZATION DEPARTMENTS

PRESENTER

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AIM

The purpose of this work is to identify the strategies that are carried out to achieve processes that promote sustainable development from sterilization worldwide departments through a review of the literature and exploring, through a survey, the tools used in the main sterilization centers in Colombia

METHODS

A free search of articles was carried out in Lilacs Scopus, Pubmed and Google Schoolar taking into account the keywords, including articles in Spanish and English to later organize the information in an analysis matrix. A survey designed through the LimeSurvey tool was carried out at eight representative sterilization departmetns of the sector in Colombia, where strategies for impact and social responsibility were inquired about.

RESULTS

Based on the research results, the state of the art of sustainability was established from the sterilization departments and the strategies designed, which focus on the development of recycling activities, optimal management of resources, design of new technologies that involve the use of solar energy and water saving, and sterilizing agents that generate less toxicity; In Colombia, the use of rational use of resources, adequate management of hazardous and non-hazardous solid waste, measurement of environmental performance, strategies to reduce the use of paper, the installation of energy-saving equipment and green purchases are mainly evidenced. Another direct impact on the population has been executed with the development of strategies for social promotion, 62.5% of the sterilization centers participate in activities such as days of surgical procedures for the vulnerable population, hand washing campaigns and patient safety, recycling and training in specific subjects in less complex institutions

CONCLUSIONS

There is currently a trend to implement strategies that are directed towards sustainable development, but it is important to recognize that sterilization practices that tend to have a lower environmental impact are not yet standardized, although initiatives and research work are being developed from each institution that show the concern of the sector on this issue and for aligning itself with the objectives of sustainable development.

References / Acknowledgements

[1] *Silvestre C. Fagoaga L. Garciandia M. Lanzeta I. Mateo M. Zapata M. Esterilización. [Internet]. Pamplona; 2000 [Citado el 20 Marzo del 2021]. Disponible en: file:///C:/Users/julie/Downloads/6428-Texto%20del%20art%C3%ADculo-10941-1-10-20090528.pdf*

[2] *Organización de las Naciones Unidas para la Alimentación y la Agricultura (FAO). Objetivos del desarrollo sostenible en América del sur. Panorama actual. [Internet]. Santiago de Chile; 2019 [Citado el 25 Marzo del 2021]. Disponible en: http://www.fao.org/3/ca3884es/ca3884es.pdf*

[3] *Rodriguez J. García C. García M. Gestión ambiental en hospitales públicos: aspectos del manejo ambiental en Colombia. [Internet]. Edición N° 4. Bogotá D.C; 2016. [Citado el 25 Marzo del 2021]. Disponible en: http://www.scielo.org.co/pdf/rfmun/v64n4/0120-0011-rfmun-64-04-00621.pdf*

[4] *Conte Grand M, D'Elia V. Desarrollo Sostenible Y Conceptos "Verdes." Problemas del Desarrollo Revista Latinoamericana de Economía [Internet]. 2018 Ene [Citado en el 15 Marzo del 2022];49(192):61–84. Disponible en: https://search.ebscohost.com/login.aspx?direct=true&db=bth&AN=126741637&lang=es&site=eds-live*

[5] *Conte Grand M, D'Elia V. Desarrollo Sostenible Y Conceptos "Verdes." Problemas del Desarrollo Revista Latinoamericana de Economía [Internet]. 2018 Ene [Citado en el 15 Marzo del 2022];49(192):61–84. e*

CONFERENCE 25 SAFE AND SUSTAINABLE DEPARTMENT

SAFETY WITHIN THE RUMED. DEBUNKING MYTHS

PRESENTER

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AIM

Even at the hospital level, we can often observe a great lack of knowledge concerning the internal working of Medical Device Reprocessing Units.
This lack of visibility often allows the surgence of myths such as the inherent danger of working in such Units, as well as the skills and competences needed to do so.
However, this is indeed a myth, since these Units work around a series of protocols, processes, and contingency plans that are standardized and allow for the design of customized labor risk prevention plans which in turn are capable of anticipating any possible perils, often to a greater degree compared to other areas in a hospital.
There is no greater danger than the danger we are not prepared to face, hence our need to anticipate any possible peril.
Aims:
General goals:
To ensure the Safety of Workers in Medical Device Reprocessing Units (RUMED).
Specific goals:
- To increase work attendance and reduce absenteeism caused by work-related accidents and illnesses.
- To collect and analyze risks associated with these types of Units and determine the preventative measures that ought to be applied to reduce and eliminate these risks.
- To protect the integrity of human and material resources, as well as the installations, the environment, and any other additional resources.
- To define an adequate internal organization of the Unit to ensure a correct management of all its resources.
- To maintain the correct levels of productivity and quality.

METHODS

Occupational Risk Prevention Plan of an operational RUMED within a large and complex Public Teaching Hospital in Madrid (Group 3), operating under the PRL Law (Prevention of Labor Risks) 31/1995, of November 8th, currently active in Spain according to European Law (Directive 89/391 EEC).
Description of Roles and Responsibilities.
Hazard identification and risk factor evaluation for each job title.
Preventative measures adopted.

RESULTS

Quicker adaptation and integration of new workers
Increase in collaboration and communication
Reduction of work-related absenteeism
Increase in productivity and work-related welfare

CONCLUSIONS

Protection of a RUMED's biggest asset: its workers
Promotion of a work culture based on safety and personal protection
The success of the risk-prevention plan depends on the implication of the workers through collaborative methodologies and debriefings.
Increase in productivity and positive outcomes in the economic balance sheet.
The plan allows for the correct organization of the Unit while respecting current laws in labor risk prevention.
The results reach higher quality standards when theoretical and practical training in labor risk prevention is accompanied by training at the operational level.
Debunking myths, determining the RUMED is one of the safest hospital areas for workers.

References / Acknowledgements

European Directive on Health and Labor Safety 89/391 EEC. - Spanish PRL Law (Prevention of Labor Risks) 31/1995

18TH – 21TH OF OCTOBER 2023

BRUXELLES

24TH WORLD STERILIZATION CONGRESS