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Learning Objectives

1. Contrast/compare the method of action for cell destruction, material compatibility and safety concerns for oxidative and cross-linking chemical agents
2. List the most common oxidative and cross-linking agents used for high-level disinfection (HLD) and sterilization of gastrointestinal flexible endoscopes
3. Define and discuss the implications of biofilm

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High-level disinfection and sterilization of GI flexible endoscopes:

Comparing oxidative and cross-linking chemical agents

by Marimargaret Reichert, RN and Tamara Struk, BA, MA, MBA

Each day thousands of gastrointestinal (GI) procedures are being performed around the world. Over 10 million GI procedures are performed in the United States annually.¹

GI diagnostic and surgical procedures are performed with sophisticated flexible endoscopes that are classified as reusable medical devices. These devices must be thoroughly cleaned and high-level disinfected or sterilized between patient procedures. This multiple step process is usually performed by specialized technicians.

Today, flexible endoscope reprocessing typically happens within the GI suite itself. The process itself and the associated equipment used for HLD or sterilization continue to evolve.

The most common chemical agents used to achieve HLD or sterilization can be categorized into two different classifications – oxidizing and cross-linking agents. In this self-study session, the differences between these chemical agents will be presented by answering the most frequently asked questions about these chemistries, their method of action, their differences and their use.

FAQ's

What is the difference between oxidative and cross-linking chemical agents?

The classification of these chemical agents is based on the way they react with a microorganism. An oxidizing agent, such as peracetic acid or PAA, kills microorganisms by chemically reacting with the microorganism's inner cell components. This chemical reaction occurs with most cellular components and causes cell death.² A cross-linking chemical agent, such as glutaraldehyde or orthophthalaldehyde (OPA), kills by chemically reacting with the microorganism's outer cell layer and causing irreversible cross-linking of proteins.³ Cross-linking of proteins "fixes" the surfaces of the cells. This process is similar to the use of formaldehyde or formalin to preserve or fixate a

tissue specimen for pathological examination. In addition to the sealing effect on the outer layers, aldehydes also inactivate enzymes to achieve kill.

The cross-linking process of these agents may attach some of the remaining microorganisms to device surfaces. This makes cleaning a critical step in endoscope reprocessing since this fixative method of action may result in layers of "build-up" of organic material and/or biofilm over time.⁶

What is the most common oxidizing agent used for GI endoscope reprocessing?

Peracetic acid (PAA) is the most common oxidizing agent for GI endoscope reprocessing. The molecular formula is C₂H₄O₃.



PAA Chemical Structure

PAA is not new. A formulation using this chemical with a specific processing system was cleared by the FDA as a low-temperature liquid sterilization agent 20 years ago. Just recently, an automated HLD process using PAA was also introduced in healthcare environments.

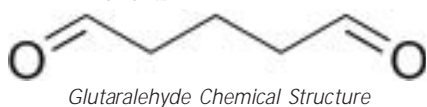
Two of the greatest attributes of PAA are its broad spectrum activity at relatively low concentrations and its safe, non-toxic by-products (a low level of acetic acid and water).³

What are the most common cross-linking agents for GI endoscope reprocessing?

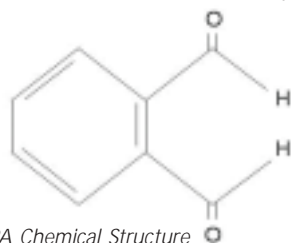
Glutaraldehyde and orthophthalaldehyde (OPA) are the most common cross-linking agents used for GI endoscope reprocessing. These chemical agents contain fewer oxygen atoms than oxidizing chemical agents.



The chemical formula for glutaraldehyde is $C_5H_8O_2$.



The chemical formula for OPA is $C_8H_6O_2$.



Aldehyde-based agents have been used for many years and remain the predominant agent for high-level disinfection of flexible endoscopes. Two of their greatest attributes are flexibility of use (e.g., can be used in either a manual or automatic process) and compatibility with the materials and adhesives used in the construction of flexible endoscopes.³

Who determines the lethality of these agents?

The U.S. Food and Drug Administration (FDA) regulates the claims for HLD and sterilization for each chemical formulation in the market. They review the results of specific required testing and, if acceptable, clear the product for market. The most common chemical agents used for HLD or sterilization of GI endoscopes and their "clearance for market" claim are listed in the following chart:

How do these chemical agents compare for material compatibility?

It is critical that the chemical agent being used for reprocessing is compatible with the materials and components of the endoscope. Flexible endoscope manufacturers have the responsibility to conduct testing and show results that demonstrate that the formulations they are recommending you use to clean and HLD or sterilize your flexible endoscopes are compatible with the materials used to construct their devices. However, as of this writing there is no standard as to the number of testing cycles or the duration of chemical exposure that allows for comparison with normal hospital use.

When oxidative agents were first introduced for endoscope reprocessing and began to replace cross-linking agents, it was perceived that they "caused" holes in the internal channel material. However, this phenomenon may be better attributed to the method of action of the two chemical agents. The repeated use of cross-linking agents may have resulted in the fixation of biological material that "plugged" or covered small pin holes. The change to oxidative agents, known for their ability to remove debris, ultimately "unplugged the plugs."

In years past, leaks occurring at the glue or adhesive joints were attributed to oxidative agents. This problem has been dramatically reduced as manufacturers have changed their glue or adhesives to those that are compatible with both oxidative and cross-linking agents.

The manufacturers of flexible endoscopes, cleaning agents and HLD / sterilization agents are all required to complete material

degradation testing. Each will make recommendations for use based on their testing results. We recommend you ask for these recommendations and question any points that are contradictory from one manufacturer to another to resolve any outstanding questions before you apply any chemical agent for scope reprocessing.

Are these chemical agents safe to use?

Under normal use conditions, and following all manufacturer guidelines, these chemical agents are safe for healthcare workers to handle and use. Appropriate personal protective equipment (PPE) is recommended to minimize exposure risk. Each facility has its own PPE policy, but professional organizations such as SGNA, APIC and AORN have also provided recommendations for guidance.

Some of the most common health effects reported for glutaraldehyde exposure in healthcare users are:

- Throat and lung irritation
- Asthma, asthma-like symptoms and breathing difficulty
- Nose irritation, sneezing and wheezing
- Nose bleed, burning eyes
- Rash, staining of hands and hives
- Headaches and nausea

In 2001, the National Institute for Occupational Safety and Health (NIOSH) published recommendations on how to minimize the risks of user exposure to glutaraldehyde.

NIOSH recommends the following:

- Using local exhaust with a minimum of 10 air exchanges per hour
- Avoiding skin contact by wearing nitrile or butyl rubber gloves

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Chemical Agent	Category	Brand Name	Company Name	High Level Disinfection	Sterilization
Peracetic Acid (PAA)	Oxidizing	STERIS 20 Sterilant Concentrate (within SYSTEM 1® Sterile Processing System)	STERIS Corporation	No indication	0.2% concentration @ 50-56°C for 12 min.
Peracetic Acid (PAA)	Oxidizing	Reliance DG™ Dry Germicide (within Reliance EPS™ Endoscope Processing System)	STERIS Corporation	0.2% concentration @ 50-56°C for 10 min. (4 minutes generation time, 6 minutes exposure time)	No indication
Glutaraldehyde	Cross-linking	Rapicide™	Medivators	2.5% concentration @ 35°C for 5 min.	2.5% concentration @ 35°C for 7 hrs and 40 min.
Glutaraldehyde	Cross-linking	Cidex™	Advanced Sterilization Products	2.4% concentration @ 25°C for 45 min.	2.4% concentration @ 25°C for 10 hrs
Orthophthalaldehyde	Cross-linking	Cidex® OPA Solution	Advanced Sterilization Products	0.55% concentration @ 25°C for 5 min. or @ 20°C for 12 min.	No Indication
Glutaraldehyde	Cross-linking	MetriCide®	Metrex Research Corporation	2.6% concentration @ 25°C for 45 min.	2.6% concentration @ 25°C for 10 hrs

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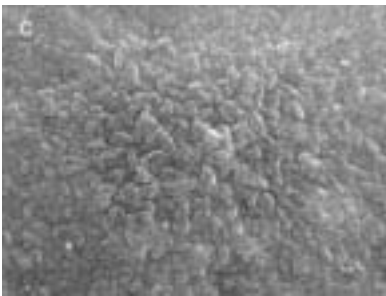


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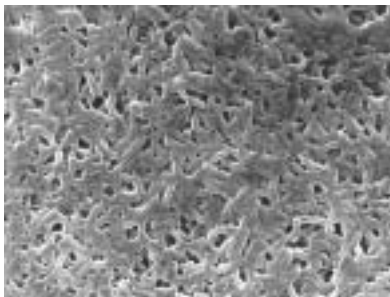
- Sealing all containers holding glutaraldehyde
- Wearing goggles when handling and using glutaraldehyde

What is biofilm?

"Biofilms are dynamic sessile microbial communities in which the organisms produce an extracellular polymeric matrix that results in a distinct structure. When growing in a biofilm, microorganisms exhibit slower growth rates and greater tolerance to antimicrobial agents. Biofilm-associated microorganisms may elicit disease processes by detachment of cells or aggregates from the device surface, production of endotoxins, or provide conditions for the development of antimicrobial-resistant organisms".¹⁰ This community of microorganisms tightly adheres to a surface and is difficult to remove. Typical microorganisms associated with biofilm formations are *Pseudomonas aeruginosa*, *Staphylococcus aureus* and *Candida albicans*.³



Laboratory grown biofilm



Why is biofilm a concern for GI endoscopy?

Biofilm contamination from inadequate cleaning is often cited as a cause of infections related to flexible endoscopes.³ Although biofilm can form on many different surfaces, it is especially problematic in devices with lumens.⁵ In addition, colonoscopes and gastroscopes, two of the most commonly used flexible endoscopes, have long and narrow lumens that pose cleaning and disinfection challenges.

What is the most effective way to reduce the risk of biofilm formation?

The most effective way to control the formation of biofilm is thorough proper and timely cleaning. According to ANSI/AAMI ST 70: 2006, "prompt cleaning reduces or eliminates the population of biofilm-forming microorganisms and thus prevents the formation of biofilm."

If a biofilm is already present, oxidizing chemical agents, like PAA, may allow for degradation and removal of the biofilm matrix from the surface area.^{3,4} ANSI/AAMI ST 70: 2006 states, "direct friction and/or oxidizing chemicals are needed to remove biofilm once formed."

Cross-linking chemical agents like glutaraldehyde or orthophthalaldehyde may affix residual debris to surfaces, making the removal of biofilm even more difficult. Cross-linking chemical agents do not support the degradation and removal of the biofilm matrix once formed and can inhibit penetration of the microorganisms found deeper in the matrix.³

Conclusion

Oxidative and cross-linking chemical agents are appropriate to high-level disinfect and sterilize flexible endoscopes. The differences between these two classifications of chemical agents are their methods of action for cell destruction, their materials compatibility and their ability to minimize the risk associated with biofilm. It's important to understand these differences before you can define your facility's needs and select the agent that is best for your patients, staff and devices. **HPN**

About the authors:

Marimargaret Reichert, RN is the executive director surgical services, Peninsula Regional Medical Center in Salisbury, MD. Reichert's areas of responsibility include OR, SDS, PACU, CSS, and GI Endoscopy.

Tamara Struk, BA, MA, MBA is product manager, sterile processing, STERIS Corporation, Mentor, OH. Struk is responsible for managing the STERIS low temperature reprocessing business, supporting both the surgical and endoscopy markets. Struk is a member of the Association of peri-Operative Registered Nurses (AORN) and the Society for Gastroenterology Nurses and Associates (SGNA).

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Comparing oxidative and cross-linking chemical agents

Circle only one answer:

- Which of the following statements is true?
 - GI endoscopes are classified as reusable medical devices
 - Most GI endoscopes can withstand high temperature reprocessing
 - The two most common classifications of chemical agents used for HLD/sterilization of flexible endoscopes are oxidizing and cross-linking agents
 - A and C
- What is the most common oxidizing chemical agent used for HLD/sterilization of G.I. flexible endoscopes?
 - Ozone
 - Peracetic acid
 - Hydrogen peroxide
 - Glutaraldehyde
- What are the most common cross-linking chemical agents used for HLD of GI flexible endoscopes?
 - Ozone and Peracetic Acid
 - Glutaraldehyde and orthophthalaldehyde
 - Glutaraldehyde and hydrogen peroxide
 - Ozone and orthophthalaldehyde
- What chemical agent kills microorganisms with an irreversible cross-linking reaction of the outer cell layer?
 - Glutaraldehyde
 - Peracetic acid
 - Orthophthalaldehyde
 - A & C
- Oxidizing agents are characterized by an abundance of what atom(s)?
 - Hydrogen
 - Oxygen
 - Nitrogen
 - Oxygen and Nitrogen
- What steps can a facility take to minimize the exposure risk of glutaraldehyde?
 - Ensure a minimum of 10 air exchanges per hour
 - Avoid skin contact by wearing nitrile or butyl rubber gloves
 - Seal all containers holding glutaraldehyde
 - Wear goggles when handling/using glutaraldehyde
 - All of the above
- Biofilm can be defined as:
 - A community of disease-forming viruses
 - A fine layer of organic matter
 - Microbial communities in which the organisms produce an extracellular polymeric matrix that results in a distinct structure
 - A fine layer of non organic material
- ANSI/AAMI states that once biofilm forms the following should be followed:
 - Direct friction and/or an oxidizing chemical should be used to remove it
 - Steam sterilization should be used at 250°F for 30 minutes
 - EtO sterilization is needed to remove it
 - None of the above
- Why is biofilm a growing concern within the GI community?
 - It affects the functionality of the device
 - It may cause severe scope damage
 - The microorganisms within the structure develop a tolerance to the microbial agents
 - All of the above
- The most effective way to eliminate biofilm is:
 - Prevent the formation with immediate and appropriate cleaning
 - Soap and water
 - Cross-linking agents
 - B & C

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