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The role of biofilms in reprocessing medical devices

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Biofilms are communities of microorganisms within extracellular polymeric material attached to surfaces. Within a biofilm, cells have some protection from drying and other stress factors in their environment, including antimicrobial agents. In this article, the challenges to medical device reprocessing posed by biofilms are addressed. Biofilm formation on reusable medical device surfaces is a risk that can be controlled. By ensuring prompt device cleaning and reprocessing either by high-level disinfection or sterilization and proper drying, biofilms will not have a chance to form. Reusable medical devices like flexible endoscopes that are promptly cleaned and disinfected, rinsed and dried pose little risk to patients.

Biofilms have been defined as communities of microorganisms attached to a surface, producing extracellular polymeric substances and exhibiting an alternate phenotype compared with corresponding planktonic cells.[1] Microorganisms in the natural world exist predominately within biofilms. Microbial growth within a biofilm is now recognized as the primary mode of microbial growth. This was widely not known until the 1970s when Costerton et al[2] published a widely read article that proposed a theory of biofilms that explained ways in which microorganisms adhere to living and nonliving materials and the benefits derived from living as attached communities.

However, much of what we know about microorganisms—their growth, structure, reproduction, resistance to chemicals, and physical stress—is from laboratory studies of planktonic cells. Although these studies have produced a vast amount of information, they have sometimes led to wrong conclusions about the way microorganisms exist and function in natural environments.[3] This article examines biofilm development on medical device surfaces and the role of microbial biofilms in device reprocessing.

BIOFILM FORMATION

Biofilm formation on the surface of a reusable medical device is not unlike biofilm formation on other surfaces and is a stepwise process beginning with preconditioning and moving on to initial reversible attachment of microorganisms, irreversible attachment, formation of microcolonies, and finally maturation of the biofilm.[4-6] In the first stage, a preconditioning basement layer of organic material is deposited on the surface of a medical device as a result of precipitation of the material from body fluids in contact with the device. Next, colonizing microorganisms proceed with initial attachment to the preconditioned surface. At this point the preconditioning film and microorganisms are loosely attached and can be easily removed by cleaning. If they are not removed by cleaning irreversible attachment begins and microorganisms begin to multiply and a mature biofilm forms. Finally, the mature biofilm will release new colonizing cells periodically to start biofilms on new surfaces downstream. All of these steps are dependent on a variety of factors, including nutrient availability, temperature, substratum topography, agitation, flow rate, and inoculum density.

PROTECTION OFFERED MICROORGANISMS INSIDE A BIOFILM

Microorganisms within a biofilm are afforded protection. Bacteria cells embedded in a biofilm are generally more resistant to inactivation using chemical agents than their planktonic (ie, free-floating) counterparts.[4,6-9] Antimicrobial agents must penetrate the biofilm matrix to reach cells. Additionally, planktonic cells utilize nutrients at a high rate of metabolism relative to cells inside a biofilm. In general, it appears that there is reduced metabolic activity in cells found deeper inside a biofilm.[4] Other advantages of life in a biofilm may include increased availability of nutrients for growth in low-nutrient environments; increased binding of water molecules, which reduces desiccation; and some protection against ultraviolet radiation. Complex biofilm consortia allows for the recycling of substances and may facilitate genetic exchange due to the proximity of cells.[10]

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Table 1
Conditions required for biofilm formation

Condition	Potable water pipe	Indwelling medical device	Reusable medical device
Colonizing microorganisms present	✓	✓	✓
Surface to be colonized	✓	✓	✓
Sufficient nutrients and water	✓	✓	✓
Temperature conditions for growth	✓	✓	✓
Time required for development of a biofilm	✓	✓	?

Table 2
Steps in endoscope reprocessing

1. PRE-CLEAN − Flush channels with detergent solution and wipe exterior endoscope surfaces at the bedside immediately following the procedure.
2. CLEAN − Bush endoscope channels with water and detergent solution.
3. HIGH-LEVEL DISINFECT/STERILIZE − Immerse endoscope and perfuse high-level disinfectant or sterilant through all channels for recommended exposure time and temperature.
4. RINSE − Rinse scope and channels with sterile water or filtered water followed by alcohol flush to assist in drying the channels.
5. DRY − Use forced air to dry insertion tube and channels.
6. STORE − Add to inventory in a way that prevents recontamination.

CONDITIONS REQUIRED FOR BIOFILM FORMATION

Specific conditions are required for biofilm formation. The major conditions are listed in Table 1. Each of the surfaces mentioned in Table 1 has common conditions that are conducive to the formation of biofilms that cannot be easily controlled—with the exception of biofilm formation time. Although little can be done in the case of an installed potable water pipe or an indwelling medical device, in the case of a reusable device the speed at which the reprocessing steps occur after use is a key factor in the prevention of biofilms.[11]

BIOFILMS AND INDWELLING MEDICAL DEVICES

Biofilm formation on an indwelling medical device can lead to serious, recalcitrant infections. Biofilm formation on a variety of indwelling medical devices, such as prosthetic heart valves, central venous catheters, urinary catheters, contact lenses, and intrauterine devices has been described.[4,12,13] Initially, cells that colonize the surface are just clusters of cells, but with time these cells produce extracellular polymeric substances that together with the cells form a true biofilm. Once devices are colonized, the biofilms that develop share fundamental characteristics of all bacterial biofilms; that is, the cells within the biofilm are protected by the extracellular matrix they produce and this protective material can decrease the effectiveness of both antibacterial molecules and host defense mechanisms.[1,12,14]

Newer approaches to prevent biofilm formation have included the development of antimicrobial-impregnated polymers and altered surface topography that inhibits initial microbial attachment. These newer approaches are mainly directed toward indwelling devices or implants and are not typically used with reusable medical devices.[15,16]

BIOFILMS AND REUSABLE MEDICAL DEVICES

Biofilm formation on reprocessable medical devices (eg, surgical instruments) occurs similarly to biofilm formation on other surfaces, but if cleaning and terminal sterilization is performed promptly after use the opportunity for biofilm formation is minimal Additionally, because most reusable instruments are used in noncontaminated, nontraumatic, and noninflamed surgical sites the associated bioburden level is low.[17] The hard surfaces of these devices are relatively easy to clean and dry. If instruments cannot be cleaned immediately after use they should be kept moist because drying will impair the cleaning process. Automatic instrument washers are very effective in removing patient soils and inactivating bacteria that can form biofilms.[18] Finally, following terminal sterilization instruments are stored in a dry environment inside packaged trays or pouches where recontamination and subsequent biofilm formation cannot occur.

ENDOSCOPES

Flexible, multichannel endoscopes are special-case reusable medical device where biofilm formation will readily occur if reprocessesing protocols are not strictly followed. The moist, nutrient-rich conditions inside the lumens of an endoscope used on a patient create a perfect environment for biofilm formation.[19] Still, some amount of time is required for cell division even under optimal conditions. Given that some gram-negative bacteria can undergo cell division every 20−30 minutes, it is likely that several hours are required before mature biofilms would develop. What is most important here is to begin the reprocessing procedure before bacteria can grow and begin to form a biofilm.[8] Reprocessing steps for flexible endoscopes (Table 2) were developed by consensus by a number of professional organizations and are commonly used.[20-23]

Removal of biofilms inside endoscope channels

Development of biofilm in endoscopes is thought to be associated with residual organic material and moisture remaining in channels as a result of inadequate endoscope reprocessing.[24,25] A study from Australia[26] revealed evidence of biofilms in the endoscopes studied, and a prospective study[26] with gastroscopes (n = 1376) and colonoscopes (n = 987) found both to be equally contaminated (1.8% and 1.9%, respectively) with low numbers of organisms commonly isolated from the nasopharynx and/or feces. The authors speculate that biofilms in endoscope channels may explain the low-level persistence of low numbers of organisms on a few endoscopes, yet conclude that the presence of organisms is unlikely to cause serious consequences in patients.

Progressive accumulation of residual organic material through repeated rounds of inadequate reprocessing has been shown in laboratory studies to decrease the effectiveness of high-level disinfectants. For example, the effect of progressive accumulation of organic material was studied[27] in laboratory experiments using the MBEC Assay (Innovotech, Edmonton, Alberta, Canada). Using this model, well-fed biofilms were grown to mimic the biofilms that can form inside flexible endoscopes that are not properly reprocessed. The conclusion was that the assurance of high-level disinfection may decrease if buildup biofilm formation develops within the channels.[27] This study emphasizes the importance of prompt endoscope cleaning, high-level disinfection, and endoscope channel drying to prevent biofilm formation.

Pineau et al[28] published a study describing the benefits of endoscope storage after reprocessing in specially designed drying cabinets. In these cabinets endoscopes channels are connected and filtered air flows through the channels ensuring adequate drying. Results of the study showed these cabinets can limit the risk of bacterial proliferation in internal channels of endoscopes during storage.

A recent study by Korvalera et al[29] confirmed the importance of drying endoscope channels after reprocessing. Using a model biofilm system in polystyrene microtitre plates they found that peracetic acid-based disinfectant was effective against the bacteria and yeasts studied, but if the drying step after disinfection was skipped regrowth could occur.

Endoscope design or manufacturing defects

Poor endoscope design or manufacturing defects can result in areas on or in endoscopes where biofilms can form and that cannot be reached by cleaning agents or disinfectants. A series of endoscope-related infections have been reported[30] associated with biofilm growing on the threads of the biopsy port of a bronchoscope underneath a cap that was supposed to be glued on by the manufacturer. Specimens obtained by swabbing these areas were positive for *Pseudomonas aeruginosa* and *Serratia marcescens.* Apart from obvious manufacturing defects that can lead to colonization of endoscope surfaces, the geometry of endoscopes presents a significant challenge for cleaning and subsequent contact of all surfaces with a high-level disinfectant.

Automatic endoscope reprocessing machines

Automatic endoscope reprocessing machines automate the various steps in endoscope reprocessing. These machines are commonly used in gastrointestinal aboratory settings because they provide consistent reprocessing for flexible endoscopes and free staff members for other work. Unfortunately, as a result of machine design flaws, there are reports[31,32] of microbial contamination (ie, biofilm formation) inside fluid channels of automatic endoscope reprocessors. Commonly associated microorganisms include *Mycobacterium sp.* and *Pseudomonas sp*.[33,34] These microorganisms, especially when growing within biofilms, sometimes exhibit resistance to disinfectants. Endoscopes disinfected in contaminated automatic endoscope reprocessing machines can become recontaminated during the rinsing steps with bacteria sloughed off from biofilms growing within the machine piping. Outbreaks and pseudo-outbreaks associated with these organisms have been reported.[35]

Proper design of automated endoscope reprocessor plumbing is critical, with special focus needed on minimization of so-call dead legs; that is, areas where standing water can reside inside in machine pipes. Automatic endoscope reprocessors with self-disinfection cycles can eliminate the risk of biofilm formation inside automatic endoscope reprocessing machine fluid channels and many modern machines now include this feature.

Additionally, appropriate connections must be made between the reprocessing machine and the endoscope to ensure that all endoscope surfaces (inside and out) come in contact with the disinfectant. Improper connections and even failure to make connections with all endoscope lumens has led to serious infections.[34]

SHOULD WE BE CONCERNED ABOUT BIOFILMS ON REUSABLE DEVICES?

Biofilm formation on medical device surfaces is a risk that can be controlled. By ensuring prompt device cleaning and reprocessing, either by high-level disinfection or sterilization and proper drying, biofilms will not have a chance to form. The time between device use and cleaning and reprocessing is key.[36] The time required for development of a mature biofilm will vary depending on many factors, but commencing cleaning and the remaining reprocessing steps within an hour after a procedure would likely prevent formation of a mature biofilm even under conditions that favor rapid development. Additionally, for high-level disinfection or sterilization processes that employ a final water rinse, complete drying is required to prevent regrowth of microorganisms on surfaces.[36-38] If established reprocessing protocols based on scientific principles are followed, the reprocessed devices will be safe to use.

CONCLUSIONS

Reusable medical devices like flexible endoscopes that are promptly cleaned and disinfected, rinsed and dried pose little risk to patients. However, bacterial biofilms can develop inside endoscope channels if established reprocessing protocols are not met and these biofilms can be difficult to remove. There are no reports in the literature directly linking an endoscope (ie, an endoscope or endoscope reprocessing machine) that has been cleaned in accordance with current reprocessing standards and not defective in design to the transmission of an infectious agent (biofilm associated or not) from 1 patient to another.[32]

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