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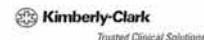
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Could *Biopsy Port Valves* be a *Source* for Potential Flexible Endoscope Contamination?

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Background

Transmission of bacteria and resulting infection between patients after flexible endoscopy is rarely observed and seldom reported. Concern in recent years has increased due to more resistant strains of bacteria, transmission of viruses, and the emergence of Creutzfeldt-Jakob disease. Effective manual cleaning and high-level disinfection of flexible endoscopes and accessories is essential to preventing the transmission of disease or infection. One component of the flexible endoscope which could harbor bacterial contamination and/or prions and is difficult to manually clean and high-level disinfect is the biopsy port valve.

Methods

A total of 15 reusable biopsy port valves were collected from three different endoscopy suites across the United States. These valves had been reprocessed per the facility's protocol and were deemed to be clean, high-level disinfected and ready for use. Each biopsy port valve was examined using brightfield microscopy (magnification of 10x). The valves were then further studied to identify potential sources of contamination using Fourier Transform Infrared Spectroscopy.

Results

Eight out of 15 (53.3 percent) biopsy port valves exhibited some form of debris or potential contamination. Additional testing confirmed the debris to be proteinaceous matter. Also, damage to many of the biopsy port valves was observed, increasing the potential for leakage and providing additional reservoirs for bacterial colonization.

Conclusion

The suspected difficulty in effectively cleaning reusable biopsy port valves has been confirmed. Considering the time required and challenges in effective cleaning and high-level disinfection of reusable biopsy port valves, single use biopsy port valves may provide a higher degree of patient safety.

Discussion

The challenges of cleaning flexible endoscopes are well recognized and documented. In fact, Martin Favero, PhD, director of scientific and clinical affairs for Advanced Sterilization Products, referred to the endoscope as "the device from hell" when discussing the difficulties in effectively cleaning and disinfecting endoscopes.¹

A 1995 Food and Drug Administration (FDA) study that examined endoscopes at 80 U.S. healthcare facilities found 38 sites having endoscopes that were deemed "clean and ready for use" but were in fact "visibly encrusted with debris."²

According to the American Society for Gastrointestinal Endoscopy (ASGE), the chances of an infectious organism being transmitted to a patient by one of these instruments is 1 in 1.8 million. David Lewis, a microbiologist with the University of Georgia, says the risk is greater. "I've calculated, just based on the amount of blood that can leak back out of the scope after it is manually cleaned, that the infection rate may be as high as several patients out of 100. I think probably the actual infection rate is somewhere in between."

Organisms such as *Pseudomonas*, *Klebsiella* Enterobacter, *Serratia*, *Salmonella*, *Proteus*, and *Helicobacter* have often been implicated in endoscope-related infections.⁴ However, studies indicate that cleaning, either manually or mechanically, can achieve a five-log reduction of contaminating microorganisms.⁵ Other studies of used surgical instruments have indicated a bioburden of less than 100 colony-forming units (CFU) of relatively non-pathogenic microorganisms to be present after standard cleaning.⁶

Additionally, in recent years there is increased concern over the naturally occurring bacteria; *Clostridium difficile* (*C. diff*) and inherent potential dangers to not only patients but staff, as well. New strains of *C. diff* are highly resistant to antibiotic therapy and can cause severe diarrhea, necrosis of the digestive tract, and, in rare instances, death.

In 2003, the ASGE and Society for Healthcare Epidemiology of America (SHEA) solicited key thought leaders from the endoscopy profession, infection control, federal and state agencies and industry leaders to create evidence-based, very specific guidelines for cleaning flexible endoscopes. The resulting Multi-Society Guideline for Reprocessing Flexible Gastrointestinal Endoscopes includes vigorous manual cleaning to remove bioburden followed by a disinfectant/sterilant soak.⁷

There is little doubt these stringent guidelines have resulted in improving the cleaning and disinfecting of the endoscopes themselves. However, some of the components and accessories used with a flexible endoscope, because of their intricate design and configuration still represent a significant challenge to effectively manually clean and high-level disinfect. One of these accessories is the biopsy port valve or inlet seal. The biopsy port valve is especially challenging to effectively manually clean and high-level disinfect because of its inherent nooks and crannies which potentially provide microbial reservoirs. (Fig. 1-2) Additionally, these reservoirs actually collect bioburden as a device is removed from the endoscope. The inner seal of the biopsy port valve is designed to "squeeze" debris from the catheter of the device.

In recent years, the biopsy port valve itself has attracted increased attention from various sources. In 2005, the British Society of Gastroenterology (BSG) has made disposable biopsy port valves a standard of care for procedures where the mucosal barrier is broken.⁸ Additionally,



Figures 1 and 2 show a cross-sectional view of a typical biopsy port valve, demonstrating the nooks and crannies as well as the inability of a cleaning brush's bristles to contact all surfaces. *Photos courtesy of US Endoscopy*

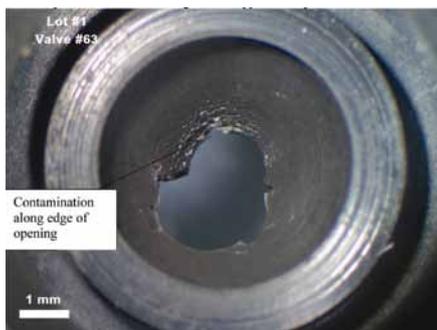


Figure 3: Valve observed during microscopy demonstrates wear and damage after use, manual cleaning, and high-level disinfection. Note the presence of contamination along the edge of the opening.

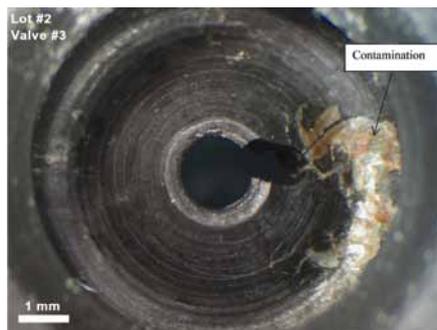


Figure 5: Valve observed during microscopy at 10x magnification. Note the presence of pinkish droplets on the edge of the valve opening, representing gross contamination.

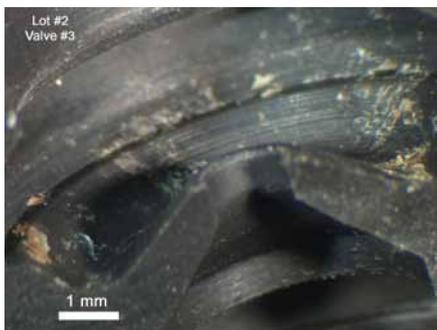


Figure 4: Internal cross-section of the valve observed at a magnification of approximately 10x demonstrates the presence of contamination in the nooks and crannies of the valve.

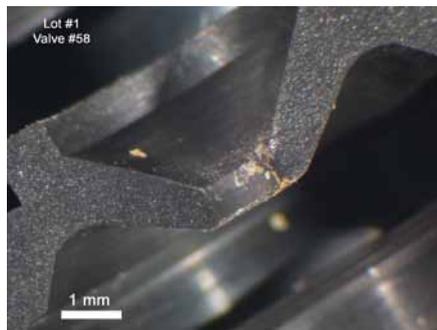


Figure 6: Internal cross-section of the valve observed at magnification approximately 10x demonstrates the presence of contamination on the internal cavity of the valve. *Photos courtesy of US Endoscopy.*

biopsy port valves and the housing around the valve have been implicated in numerous post-bronchoscopy infections, some of which resulted in death.⁹ As a result, all biopsy port valves used on bronchoscopes are now recommended for single patient use only. Finally, it is an ASGE standard that "all devices that breach the mucosal barrier (i.e., forceps, snares, injection needles or critical devices) be sterile."¹⁰

In an attempt to quantify the potential for biopsy port valves to be contaminated and harbor bacteria NAMS Advisory Services (NAS) an independent, nationally recognized consulting and testing laboratory, was retained. Biopsy port

valves which were deemed to be clean, high-level disinfected, and "ready for use" were collected from three different GI labs within hospitals or ambulatory surgery centers around the United States. The valves were cleanly packaged and shipped to NAS. NAS then forwarded the samples to Richard S. Brown, MS, D-ABC, of MVA Scientific Consultants. Brown holds a master of science degree in forensic chemistry and was a research microscopist at McCrone Environmental Services, and a senior criminologist with the Orange County Sheriff-Coroner Department in Santa Ana, Calif. Brown examined and photo-documented the condition of the valves. Each valve is

cross-sectioned, imaged on the front and back of the orifice. The valve is tiled in different directions to highlight different features. He summarized his study as follows: Three samples of closed Zip-lock bags, each containing five biopsy port valves, were received for imaging. Each sample set was assigned an MVA Scientific Consultants sample number. Numbers molded on each valve were used to identify each valve individually. The work was performed Jan. 25-30, 2006.

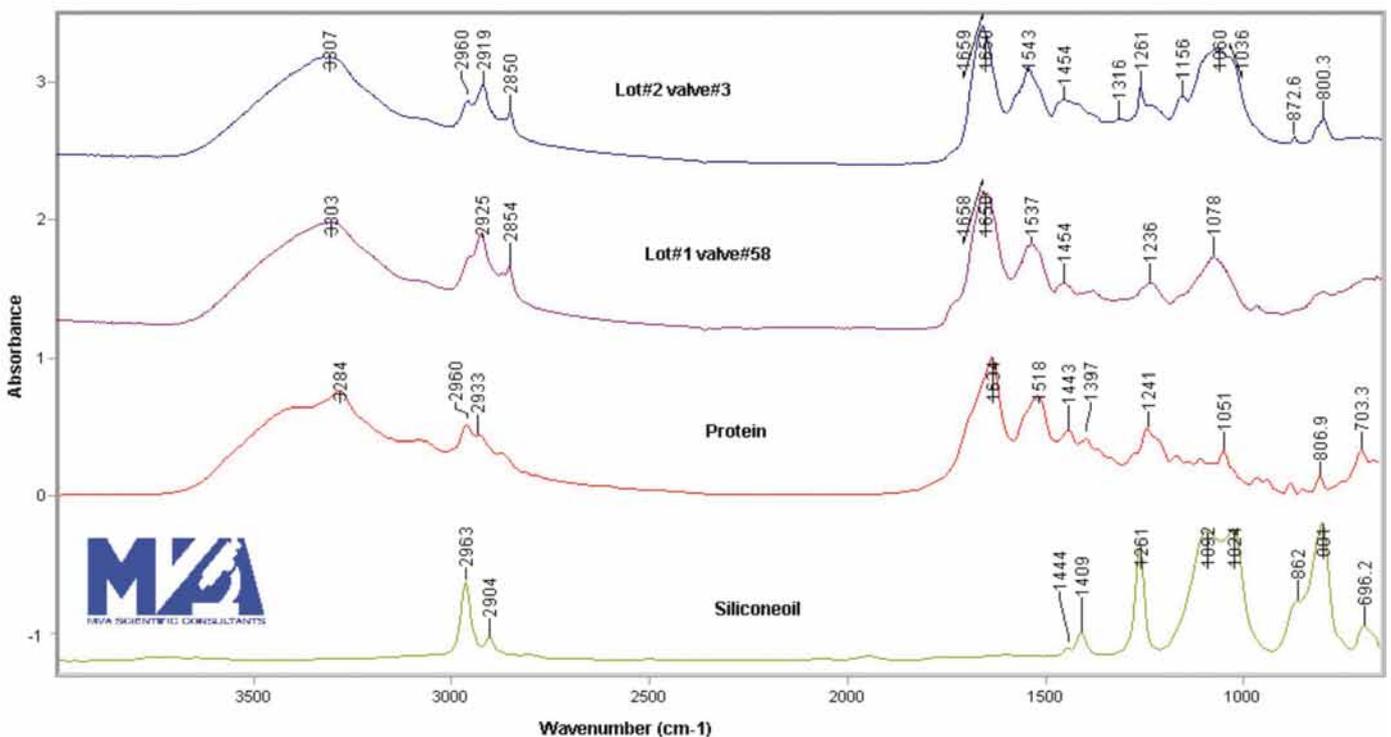
Each valve consisted of an attached cap and a valve body with a circular opening. Images of the circular opening were collected from opposite sides using reflected brightfield microscopy at an original magnification of approximately 10x. Images were collected using the same lighting conditions and magnification. A total of two cross-sectioned images were collected from each valve. Debris or foreign matter was observed contaminating a total of eight of the 15 valves. Of the eight contaminated valves, at least one valve came from each of the three facilities. Also, many of the valves exhibited damage to the circular opening within the valve body.

What does this all mean?

AAMI Technical Information Report (TIR) 30:2003: A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices states, "Manually cleaning and high-level disinfecting a device is the critical first step in reprocessing any device after it has been used on a patient. Failure to remove foreign material (e.g., soil, organic and inorganic materials, lubricants, microorganisms) from both the outside and the inside of the device can interfere with the effectiveness of subsequent disinfection and/or sterilization."

Inability to effectively remove this debris represents a significant problem. Furthermore, what exactly is the contamination on the valves? To answer this question two of the eight contaminated valves were selected for further study. The contamination on the valves was analyzed using Fourier Transform Infrared Spectroscopy (FTIR).

This result is similar to a human fingerprint in that it is rather unique and descriptive of the material being analyzed. The top two graphs are the "fingerprints" from the contamination on two of the valves. The third graph is the "fingerprint" for protein, which you would expect to see with organic contamination emanating from the human body. Note how the "fingerprint" from contamination on the two valves is very similar to the protein "fingerprint" which we would normally not expect to find on the valve but we would expect to find as contamination from use. Also note that the contamination is very different from the FTIR spectra for silicone oil, which you might expect to find on this device. These findings show that the unknown substance is truly contamination and does not belong on the valve.



The result of the FTIR analysis.

This could be a dangerous situation. Not only is organic matter from a human source present on the valves, but there is significant wear which complicates the ability to clean the valves because of the increased presence of tears, holes, and crevices where bacteria can grow and become more difficult to remove. Moreover, the organic matter provides a breeding ground for bacteria to grow and protects it from the lethal effects of cleaning, disinfection, and sterilization, which can sustain the growth of bacteria allowing them to be present in significant numbers when the product is reused. If a device such as this is contaminated with Salmonella, Serratia, and Klebsiella etc., the chance of a nosocomial infection is dramatically increased.

Dr. Armin Ernst, director of interventional pulmonology at Beth Israel Deaconess Medical Center in Boston, points out new scope technologies might offer ways of reducing the risk of spreading infections. "Every time humans are involved, human error is a potential, I think we need to pursue other avenues. For example, disposable guides, disposable sheaths, disposable instruments even, since that will be the ultimate in safety."¹¹ Jane Tillet of the Endoscopy Unit at the University Hospital of Wales in Heath Park, Cardiff, Wales presented a paper at the 8th European Conference of the European Society of Gastroenterology and Endoscopy Nurses and Associates (ESGENA) titled, "The Implications of Change in Decontamination of Equipment for Gastrointestinal Endoscopy" and concluded, "biopsy inlet seals should be discarded after the insertion of biopsy forceps, wires and snares. There are legal implications, patient safety and evidence

to support change in good ethical practice."¹²

In summary, the results show that 53.3 percent of the biopsy port valves used in this study were contaminated upon advanced scientific review, despite being reprocessed per their facility's protocol and deemed clean, high-level disinfected and ready for use. In addition to the risk for human error, the inability of cleaning brush bristles to reach hidden nooks and crannies within the ornate structure of biopsy port valves can prevent adequate manual cleaning and subsequent high-level disinfection. Therefore, despite following stringent reprocessing guidelines, contamination is still possible. Further, wear and tear found on reused biopsy port valves compromises their structural integrity, allowing for potential leakage of bodily fluids on healthcare staff. Changing practice to single-use biopsy port valves may offer a safer alternative for patients and healthcare staff.

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