American Journal of Infection Control 47 (2019) 666–670

Contents lists available at ScienceDirect

American Journal of Infection Control

journal homepage: www.ajicjournal.org

Major Article

Widespread clinical use of simethicone, insoluble lubricants, and tissue glue during endoscopy: A call to action for infection preventionists

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Key Words:
Endoscope
Silicone
Reprocessing

Background: Current methods for reprocessing flexible endoscopes do not consistently eliminate organic soil. The off-label use of simethicone as a defoaming agent may contribute to reprocessing failures, and endoscope manufacturers have cautioned against its use.

Methods: We sought evidence of simethicone use by interviewing hospital personnel, conducting audits, inspecting endoscopes, and conducting tests.

Results: Researchers examined 69 fully reprocessed endoscopes in 4 hospitals. Microbial cultures were positive for ≥50% of endoscopes. Researchers observed cloudy, shimmery fluid resembling simethicone inside channels and under a duodenoscope elevator mechanism. Crystallized white fragments were observed protruding from a gastroscope water jet outlet. Oily, sticky residue was found on endoscopes, and a 3-dimensional mass was found inside an endoscopic ultrasound endoscope. Hospital personnel reported the use of simethicone, cooking oil and silicone sprays, and tissue glue during endoscopy.

Discussion: The off-label use of defoaming agents, lubricants, and tissue glue is common and many endoscopists consider these products essential. Our findings suggest these substances are not removed during reprocessing and may impact reprocessing effectiveness.

Conclusions: Infection preventionists should determine whether these products are used in their institutions and evaluate methods for removing them. New policies may be needed to support procedural success and effective endoscope reprocessing.

Flexible endoscopes are generally reprocessed using high-level disinfectants (HLD) that theoretically eliminate all microbes with the exception of resilient spore-forming bacteria.[1-3] However, in practice, current reprocessing methods are not effective at eliminating organic soil or microbes.[4-10] Although this may be due, in part, to the complex nature of endoscope reprocessing[1,2,11,12] and non-adherence with reprocessing guidelines,[5,13,14] researchers have recently documented reprocessing failures even when technicians reportedly followed national guidelines and manufacturer instructions.[9,14-16]

For decades, it was believed that there was very little risk of infection associated with endoscopy.[17,18] However, recent research has determined that the risk of endoscopy-associated infection is substantial (0.1% to ≥4% of patients) even when prophylactic antimicrobials are prescribed.[18-20] Unfortunately, outbreaks have occurred in settings without any known deficiencies in practices, and infections involving multidrug-resistant pathogens continue to occur.[21-23] Although sterilizing endoscopes seemed like a promising solution because it has a wider margin of error than HLD,[23] recent studies have detected reprocessing failures even when hydrogen peroxide gas[24] or ethylene oxide gas were used.[25,26] These sterilization failures could be because of insufficient cleaning or damage caused by procedural use or exposure to reprocessing chemicals.[24-26]

These reprocessing failures raise the possibility that something may be interfering with the effectiveness of cleaning and HLD. Several studies have found that most endoscopes have visible scratches, gouges, dents, or other surface irregularities.[5,9,10,14,24,27] Damaged surfaces are difficult to clean and provide a safe haven for biofilm.[28]

In addition to visible defects, our team has frequently observed retained fluid and residues that are viscous, oily, sticky, and sometimes

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Funding/support: Healthmark and 3M Company provided financial support, materials, and laboratory services for the studies described in this manuscript. The sponsors did not have input on study design, data collection, analysis, interpretation of findings, or the content of this manuscript. The authors have also received research grants, study materials, or consulting contracts from 3M Company, Ambu, Auris Health, Advanced Sterilization Products, Boston Scientific, Laborie/Cogentix, Convergascent, Fortive, Healthmark, Medivators, Nanosonics, and Steris.

Conflicts of interest: None to report.

https://doi.org/10.1016/j.ajic.2019.02.012

opaque (white, pink, or shimmery) in fully reprocessed endoscopes. During a study performed in an ambulatory surgery center in 2016, our team discovered that droplets observed inside endoscope ports and channels contained simethicone (silicone). Laboratory analysis found the substance matched the simethicone in infant gas relief drops that were used during gastrointestinal endoscopy to reduce foam and improve visibility.[29] Simethicone is hydrophobic and insoluble in water,[29] and crystallized simethicone has been found by others inside endoscope channels even after vigorous cleaning and HLD.[30]

This manuscript describes research we conducted to evaluate the effectiveness of endoscope reprocessing and identify factors that may be impeding successful reprocessing. As anticipated, simethicone residues were found. In addition, we unexpectedly discovered that endoscopes are commonly exposed to other substances that interfere with reprocessing effectiveness and remain on patient-ready endoscopes. The goal of this manuscript is to explain how these discoveries were made and encourage further research on the prevalence and impact of insoluble substance use during endoscopy.

METHODS

In 2017, we conducted prospective, multisite studies to evaluate the effectiveness of bronchoscope reprocessing and the methods used to dry flexible endoscopes. The study sites were 4 hospitals located in East Coast, West Coast, and Midwestern states. No human subjects were involved, and hospital administrators and institutional review boards categorized the studies as quality improvement initiatives that did not require review.

Reprocessing practices, study methods, and the results for primary endpoints have been previously described.[5,14] In brief, samples were obtained for microbial cultures and tests for residual organic soil (adenosine triphosphate [ATP], protein, and hemoglobin). Researchers interviewed personnel and conducted systematic audits of reprocessing practices using structured checklists. In addition, researchers systematically inspected exterior surfaces of patient-ready endoscopes using a digital camera capable of magnification (iPhone; Apple, Cupertino, CA) and examined interiors of ports and channels using borescopes (0.8 mm Ultra-Thin HQ Micro Borescope; Medit, Inc, Winnipeg, Canada; 2.3 and 3.2 mm Flexible Inspection Scope; Healthmark Industries, Fraser, MI). Photographs were taken whenever fluid droplets, sticky residue, debris, surface damage, or other irregularities were observed. Researchers and reprocessing personnel attempted to remove residue using sterile swabs or brushes whenever it was accessible, and fluid droplets were tested for the presence of water using Hydrion Humidicator Paper (Micro Essential Laboratory, Inc, Brooklyn, NY).

RESULTS

During these 2 studies, researchers examined a total of 69 endoscopes, including 21 bronchoscopes, 13 colonoscopes, 12 gastroscopes, 7 endobronchial ultrasound bronchoscopes, 5 duodenoscopes, 3 cystoscopes, 3 ureteroscopes, 3 endoscopic ultrasound endoscopes, and 2 intubation scopes. As previously reported, residual fluid was found in 22 of 45 (49%) fully reprocessed endoscopes in the drying study. Microbial growth was detected in 32 (71%). Mold and pathogens including *Stenotrophomonas maltophilia* and *Citrobacter freundii* were found. Substantial defects were observed in 100% of endoscopes during visual inspections performed during the drying study.[5] Findings were similar in the bronchoscope study. Microbial growth was detected in 14 of 24 (58%) fully reprocessed bronchoscopes. Mold and pathogens including *S maltophilia* and *Escherichia coli/Shigella* were found. Visible irregularities were observed in 100% of bronchoscopes, and biochemical tests detected substantial organic soil in 100% of bronchoscopes.[14]

Simethicone

The hospitals reported using various brands of infant gas relief drops containing simethicone to improve visibility during gastrointestinal procedures. Cloudy, white, shimmery fluid resembling simethicone was observed in endoscope channels (Fig 1A), and under the elevator mechanism of a duodenoscope (Fig 1B) after being fully reprocessed.

All visible droplets harvested from channels tested positive for water. This was expected because water is an ingredient in simethicone gas relief drops.[31] The white droplet observed in the duodenoscope elevator mechanism (Fig 1B) could not be captured for testing owing to its small size and location. However, samples taken from the elevator area after HLD had *Sphingomonas phyllosphaerae* colonies that were too numerous to count and an ATP level of 1,572 relative light units (RLUs), which is far higher than the 200 RLU benchmark for manually cleaned endoscopes.

In addition to viscous white fluid, we observed other residue that resembled crystallized simethicone described by other researchers.[30] Hospital personnel reported adding simethicone to sterile water used for irrigation during procedures, and 1 fully reprocessed gastroscope had a solid white mass protruding from the waterjet channel (Fig 2). Researchers were unable to extricate the white mass from the waterjet channel outlet for testing, and reprocessing technicians reported multiple efforts with brushes and other instruments were needed to remove it. ATP testing detected substantial contamination (342 RLU), and the gastroscope harbored *S maltophilia*.

Other lubricants and silicone-containing products

Oily residue was frequently seen on external surfaces of endoscopes, most commonly near the instrument channel port (Fig 3).

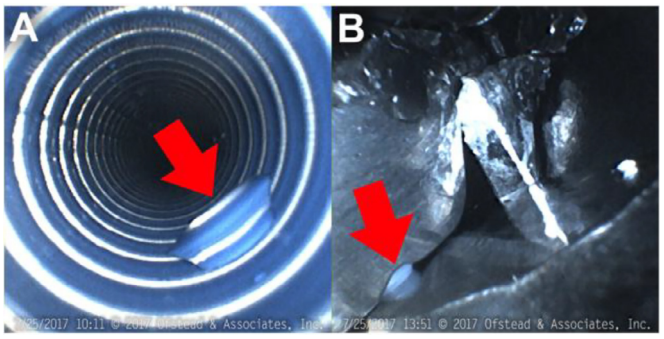

Fig 1. Simethicone droplets in a (A) gastroscope channel and (B) duodenoscope elevator mechanism.

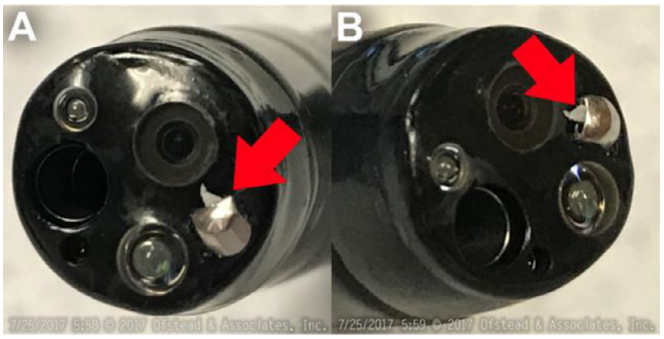

Fig 2. Substance resembling crystallized simethicone protruding from the distal end water jet of a gastroscope (A,B).

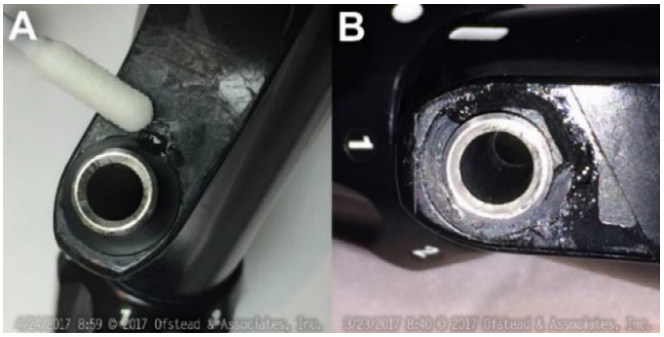

Fig 3. Oily, sticky residue near the instrument ports (A,B) on 2 colonoscopes.

This residue was tacky, tested negative for water, and smeared but could not be removed with sterile swabs.

While visiting procedure rooms and supply areas at study sites, our research team noted a variety of commercial products that were reportedly being used as lubricants or defoaming agents during endoscopic procedures. These included various brands of infant gas relief drops, as well as Rusch Silkospray Universal Silicone Spray (Teleflex; Wayne, PA), Pam cooking spray (ConAgra Brands; Chicago, IL), and HyVee-brand vegetable oil spray (HyVee; West Des Moines, IA) (Fig 4). According to product labels, Silkospray contains an aerosolized medical-grade silicone oil that is sprayed on surgical instruments to provide lubrication during procedures.[32] The cooking sprays are not labelled for medical use and their labels stated that they contain soybean, palm, coconut, and/or canola oils; lecithin (a non-stick agent); and dimethyl silicone (an antifoaming agent). Pam cooking spray also contains a rosemary extract that serves as a preservative. Infection preventionists and reprocessing personnel at the study sites reported that they had not been consulted about the use of these products.

Tissue glue

Inside the biopsy port of an endoscopic ultrasound endoscope, a rigid 3-dimensional mass protruded into the channel from a hardened puddle of fluid adhered to the channel wall (Fig 5). The mass had an unusual shape and did not resemble simethicone products in use at the facility. Despite substantial efforts, we were unable to dislodge the substance for testing. Reprocessing personnel inspected the mass and identified it as tissue glue used during endoscopic procedures to stop bleeding. They had previously experienced difficulty removing tissue glue from endoscopes. Interviews with personnel at the other study sites confirmed that clinicians occasionally use tissue glue during endoscopic procedures, and said it was difficult or impossible for reprocessing technicians to remove.

DISCUSSION

During site visits in 4 hospitals, our research team unexpectedly observed foreign substances on surfaces of fully reprocessed endoscopes. We discussed our observations with site personnel and learned that tissue glue, lubricants containing oil and silicone, and simethicone (infant gas relief drops used as defoaming agents) were commonly used during endoscopy in these hospitals. To evaluate the implications of such product use, we conducted literature searches and reviewed endoscope reprocessing guidelines and manufacturers' instructions for use.

The use of simethicone appears to be ubiquitous during endoscopy,[33-35] and simethicone residues have been found inside fully reprocessed endoscopes in several institutions.[29,30,36] Researchers in the Netherlands recently reported simethicone residue had crystallized inside all of their colonoscopes, and they were unable to remove it with warm water, detergent, or peracetic acid.[30] A team at Stanford inspected endoscope channels after flushing with various concentrations of simethicone and found that "clear and semi-opalescent drops" were still present in the channel after standard reprocessing.[36] Their spectroscopic analysis confirmed the presence of simethicone inside endoscopes after reprocessing, even at the lowest concentration of simethicone used for procedures during the study.

After observing Silkospray canisters in the bronchoscopy units of 2 hospitals, we obtained a peer-reviewed article describing the use of Silkospray for lubrication during bronchoscopy.[37] In addition, internet searches identified an academic white paper from the University of Wisconsin that described patient safety and occupational health risks associated with Silkospray use. These included potential inhalation of aerosolized silicone, slippery work surfaces, and cryogenic burns caused by rapid vaporization of propellants such as butane and propane.[38]

There were no peer-reviewed journal articles or white papers describing the use of consumer products such as Pam or HyVee cooking sprays during endoscopy. However, we were able to find a 2010 customer letter released by Olympus that addressed the use of Pam cooking spray with their endoscopes.[39] This letter recommended the use of water-based lubricants and cautioned against using petroleum- or silicone-based lubricants. Olympus acknowledged that Pam cooking spray was being used in the field and said it appeared to be compatible with their flexible endoscopes. More recently, Olympus strongly recommended against the use of any products containing simethicone or silicone.[40] The 2018 warning from Olympus states that facilities should conduct risk assessments if physicians wish to use silicone-containing products against manufacturer recommendations. Olympus stated that

Fig 4. Lubricants present at study sites, including (A) infant gas relief drops; (B) Silkospray; and (C) vegetable oil-based cooking sprays that contain silicone.

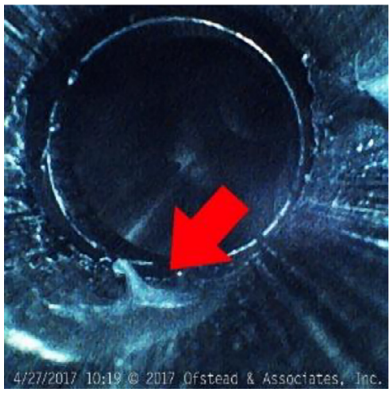

Fig 5. Solid mass protruding into the channel of an endoscopic ultrasound endoscope.

simethicone and silicone can persist on endoscopes and affect reprocessing effectiveness, and oil or petroleum-based lubricants may damage the endoscope. Other endoscope manufacturers including Fujinon and Pentax have also recommended against the use of simethicone-based defoaming products.[41,42] Despite these recommendations, in 2018, the Food and Drug Administration (FDA) released 2 adverse event reports about white residue on endoscopes[43] and yellow residue in automated endoscope reprocessors[44] that tested positive for silicone.

Reprocessing personnel suspected a 3-dimensional mass we observed inside an endoscope was solidified tissue glue. We subsequently learned that the use of tissue glue in endoscopy is considered off-label.[45,46] However, our literature searches identified numerous peer-reviewed journal articles that described the use of cyanoacrylate and fibrin tissue glue for endoscopic treatment of bleeding lesions.[45-48] These sources reported that tissue glue rapidly hardens and can stick to endoscope channels and instruments during use, becoming difficult to remove during reprocessing.[47,48] The American Society for Gastrointestinal Endoscopy acknowledged in a 2013 position statement that the use of tissue glue may ruin endoscopes, saying "Damage to the endoscope can sometimes be repaired but may require disposal and replacement of the entire instrument."[46] To prevent tissue glue adherence to the endoscope, some clinicians coat the endoscope with poppy seed oil[46-48] or silicone oil.[46] Our searches identified 2 FDA reports of adhesive residue remaining in endoscopes,[43,49] and these suggest that other types of adhesives may come in contact with endoscopes.

Because of the insoluble, hydrophobic nature of silicone- and oil-based products, and the rapid adhesion of tissue glue to surfaces, enhanced reprocessing measures are unlikely to be successful in removing these substances from endoscopes. Nevertheless, endoscopists and bronchoscopy laboratory personnel at our study sites stated they hoped that additional rinsing and scrubbing by reprocessing technicians would remove the residues. In contrast, sterile processing personnel reported that the use of these insoluble products increased the difficulty of manual cleaning and contributed to reprocessing failures and a need for repairs. Given the nature of the foreign substances observed on endoscopes during this study, we share their concern that simethicone, lubricants, and tissue glue are remaining on endoscopes in spite of rigorous efforts to remove them.

This study has several limitations. The study size was small, and the findings may not be generalizable. Our audits did not include all departments where endoscopes were used or reprocessing was performed, and we may not have identified all products that could impact endoscope durability and reprocessing effectiveness. We did not anticipate observing any foreign substances other than simethicone, and the study protocol did not include methods for capturing or testing the oily residues or solid mass found inside endoscopes during this study. Therefore, we cannot be sure whether the substances observed were the simethicone, silicone spray, cooking oil sprays, or tissue glue in use at the participating hospitals, or something else that was not discovered during the study site visits. More research is needed to determine the prevalence of usage for these and other off-label products and their impact on reprocessing effectiveness and clinical outcomes.

CONCLUSIONS

Our findings revealed that the use of defoaming agents, lubricants, and adhesives during endoscopy is widespread.[29,30,36,37,46,48] More research is needed to determine the impact of these substances on reprocessing effectiveness and patient safety. In the meantime, there are numerous ways for infection preventionists and technicians to learn about the use of these products in their institutions:

1. Visit procedure rooms and stock rooms to identify which products are currently in use.
2. Interview clinicians about lubricants, defoaming agents, and tissue glue used during endoscopy.
3. Review purchasing records to determine whether any of these products have been ordered and, if so, inquire about their use during endoscopy.
4. Determine what visual inspection practices are in place to visualize endoscope interiors.
5. Ask reprocessing technicians if they observe sticky residue or have trouble removing oily, sticky, or opaque substances from endoscopes.
6. Examine the exteriors and interiors of endoscopes to identify oily, sticky, or 3-dimensional residues.
7. Request recommendations from endoscope manufacturers regarding compatible products and methods for removing any residue found.

Once this information is compiled, institutions should conduct a risk assessment with all involved stakeholders, including clinicians, reprocessing personnel, infection preventionists, risk management, and administration. The risk assessment should consider clinician input regarding the necessity of these products to enable clear visualization and instrument use during endoscopy. In tandem, consideration should be given to methods for protecting and maintaining reusable endoscopes that are exposed to these substances or new technology such as endoscopes that are disposable or able to be disassembled. Doing so will maximize procedural success, preserve the endoscope, and protect patients from exposure to off-label substances and residual contamination that may be harbored by the presence of insoluble substances.

Acknowledgements

We are grateful for the contributions of study site personnel who provided insights regarding the off-label use of products that may interfere with reprocessing effectiveness. We also acknowledge Brandy Buro and Melissa Anderson for proofreading this manuscript prior to submission.

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