Evidence appraisal of Brock AS, Steed LL, Freeman J, Garry B, Malpas P, Cotton P. **Endoscope storage time: assessment of microbial colonization up to 21 days after reprocessing.** *Gastrointest Endosc.* 2015;81(5):1150-1154.

Evidence Appraisal Score: III B

Editor's note: *Reading research and incorporating valid research results into practice is a vital part of ensuring that perioperative nursing practice is evidence based. The AORN Research Evidence Appraisal Tool, which was adapted with permission from the Johns Hopkins Evidence-Based Practice Model and Guidelines, can help perioperative nurses evaluate research. This tool is used to evaluate the evidence upon which AORN's guidelines are based. The tool can be used to appraise the level of evidence and quality of evidence for a single research study or a summary of multiple research studies. An abbreviated tool using only the sections of the tool relevant to the study appraised is included in this article. Each section of the tool is discussed to help readers understand why the study received a particular appraisal score and what that rating means to perioperative nursing practice. Clinical judgment should be used to determine whether the findings of an individual study are of value and relevance in a particular setting or patient care situation. Individuals intending to put this study's findings into practice are encouraged to review the original article to determine its applicability to their setting.*

According to the Spaulding classification system, endoscopes (including duodenoscopes, gastroscopes, and colonoscopes) are semicritical devices because they come into contact with mucous membranes but do not breach the sterile environment. Consequently, to prevent the transmission of infection from patient to patient, as recommended by multiple societies, endoscopes must be

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reprocessed after each use via a high-level disinfection process. Although high-level disinfection protocols are highly effective when applied diligently, it is unknown how long reprocessed endoscopes may be stored before microbial colonization begins to occur. Currently, there is variability in the reprocessing interval among institutions, with many institutions using intervals of five to seven days, while others reprocess after 12 to 72 hours depending on the type of endoscope. Given the paucity of information on how long endoscopes may be stored before microbial colonization occurs, the aim of this prospective observational study was to demonstrate whether duodenoscopes, gastroscopes, and colonoscopes may be stored after reprocessing for as long as 21 days without microbial colonization by potential pathogenic microorganisms. This study was given exempt status by the Institutional Review Board of the Medical University of South Carolina because it did not include human subjects or identifiers.

LEVEL OF EVIDENCE: STUDY

Because this is the report of a nonexperimental, prospective, observational study, the Level of Evidence: Study portion of the AORN Research Evidence Appraisal Tool was used to appraise this study (Figure 1).

Setting. The setting was a tertiary care center in Charleston, South Carolina.

Sample size and composition. Two RNs collected microbial samples from each endoscope channel in four duodenoscopes, four colonoscopes, and two gastroscopes immediately after the endoscopes were reprocessed via high-level disinfection. After reprocessing, the endoscopes were stored hanging in a dust-free cabinet. On days seven, 14, and 21, the RNs removed the endoscopes from the cabinet and resampled them without reprocessing.

Interventions. No interventions were used.

Control. No controls were used.

Random assignment. There were no random assignments.

Level of evidence. When using the AORN Research Evidence Appraisal Tool, this study was classified as III for level of evidence because it was a single, nonexperimental, prospective, observational study.

QUALITY OF EVIDENCE: STUDY

Because this is the report of a nonexperimental, prospective, observational study, the Quality of Evidence: Study portion of the AORN Research Evidence Appraisal Tool was used to appraise this study.

Existing information. The researchers described existing information, which revealed that exogenous transmission of infection via endoscopy is a rare event when proper high-level disinfection techniques are used. However, there is a paucity of information regarding how long endoscopes may be stored before microbial colonization occurs. Currently, multisociety guidelines in the United States do not provide recommendations for how long endoscopes may be stored after reprocessing; this has resulted in variability in reprocessing intervals among institutions, with many using intervals of five to seven days. The few studies that have addressed the issue suggest that storing endoscopes for five to 15 days is associated with a low risk of contamination:

- One small study of colonoscopies only showed no pathogens for up to eight weeks.
- Another study demonstrated no clinically significant growth on gastroscopes, colonoscopes, or duodenoscopes at five days.
- In another study, no pathogens or potential pathogens were recovered on three colonoscopes or four duodenoscopes at 14 days.
- Two studies evaluating colonoscopes alone demonstrated no clinically significant contamination at seven days.
- A larger study involving 23 endoscopes of different types showed no potential or true pathogens after five days and only one (ie, yeast) when the incubation was extended to seven days.
- A recent study evaluating four colonoscopes during an eight-week period found no pathogens; however, that study was limited to colonoscopes, and fungal cultures were not obtained.

Purpose of the study. The purpose of the study was clearly stated—to demonstrate whether flexible endoscopes may be stored without colonization by pathogenic microorganisms for as long as 21 days after they have been reprocessed using high-level disinfection techniques.

Literature review. The literature review was current. Of the 13 works cited, seven (54%) were published within the previous five years.

Sample sufficiency. The sample size, 96 microbial samples collected from the channels of 10 endoscopes, appears to be adequate for the study design (ie, nonexperimental, prospective, observational study).

Control group. There was no control group in this study.

AORN RESEARCH EVIDENCE APPRAISAL TOOL

DATE	5/28/2015
REVIEWER	George Allen
APPRAISAL SCORE	III B

RW# | CITATION Brock AS, Steed LL, Freeman J, et al. Endoscope storage time: assessment of microbial colonization up to 21 days after reprocessing. Gastrointest Endosc. 2015;81(5):1150-1154.

Does this evidence address the perioperative practice question? ☑ Yes ☐ No – Do not proceed with evidence appraisal.

LEVEL OF EVIDENCE: STUDY

Report of a single research study? ☑ Yes ☐ No (If No, go to Summary)

SETTING Tertiary care center in Charleston, South Carolina

SAMPLE SIZE 10 Endoscopes | COMPOSITION 4 duodenoscopes, 4 colonoscopes, and 2 gastroscopes

INTERVENTION(S) ☐ Yes ☑ No | CONTROL ☐ Yes ☑ No | RANDOM ASSIGNMENT ☐ Yes ☑ No

YES to Intervention, Control and Random Assignment	☐	LEVEL I Randomized Controlled Trial (RCT) or Experimental Study
YES to Intervention and either Control or Random Assignment	☐	LEVEL II Quasi-Experimental (no manipulation of independent variable; may have Random Assignment or Control)
YES to Intervention only or NO to Intervention, Control and Random Assignment	☑	LEVEL III Non-Experimental (no manipulation of independent variable; includes descriptive, comparative, and correlational studies; uses secondary data)
	☐	LEVEL III Qualitative (exploratory [eg, interviews, focus groups]) starting point for studies where little research exists; small samples sizes; results used to design empirical studies)

QUALITY OF EVIDENCE: STUDY

Does the researcher identify what is known and not known about the problem and how the study will address any gaps in knowledge?	☑ Yes	☐ No	
Was the purpose of the study clearly presented?	☑ Yes	☐ No	
Was the literature review current (most sources within last 5 years or classic)?	☑ Yes	☐ No	
Was sample size sufficient based on study design and rationale?	☑ Yes	☐ No	
If there is a control group: • Were the characteristics and/or demographics similar in both the Control and Intervention groups? • If multiple settings were used, were the settings similar? • Were all groups treated equally except for the Intervention group(s)?	☐ Yes ☐ Yes ☐ Yes	☐ No ☐ No ☐ No	☑ NA ☑ NA ☑ NA
Are data collection methods described clearly?	☑ Yes	☐ No	☐ NA
Was instrument validity discussed?	☐ Yes	☐ No	☑ NA
Were the instruments reliable (eg, Cronbach's $\alpha \geq 0.70$)?	☐ Yes	☐ No	☑ NA
If surveys/questionnaires were used, was the response rate ≥ 25%?	☐ Yes	☐ No	☑ NA
If tables were presented, was the narrative consistent with the table content?	☑ Yes	☐ No	☐ NA
Were the results presented clearly?	☑ Yes	☐ No	
Were conclusions based on results?	☑ Yes	☐ No	
Were study limitations identified and addressed?	☐ Yes	☑ No	

A HIGH	Consistent, generalizable results Sufficient sample size Adequate control Definitive conclusions Consistent recommendations based on comprehensive literature review that includes thorough reference to scientific evidence	☐
B GOOD	Reasonably consistent results Sufficient sample size for the study design Some control Fairly definitive conclusions Reasonably consistent recommendations based on fairly comprehensive literature review that includes some reference to scientific evidence	☑
C LOW QUALITY OR MAJOR FLAWS	Little evidence with inconsistent results Insufficient sample size for the study design Conclusions cannot be drawn	☐

ADDITIONAL COMMENTS:

Figure.

Data collection. The researchers clearly described the methods of data collection. Two RNs collected all microbial samples from each channel in three types of endoscopes: four duodenoscopes, four colonoscopes, and two gastroscopes. For the duodenoscopes, the nurses first collected samples from the elevator wire channel, followed by the suction channel and biopsy port. The latter two were collected in the same order for the colonoscopes and gastroscopes. For the elevator channel, the RNs used a 3-mL Luer-Lok™ syringe to irrigate with 3 mL of sterile water three times, for a total collection of 9 mL. The RNs used the same sample collection procedure for the suction and biopsy ports, whereby they first irrigated with 30 mL of sterile water and then inserted a sterile brush through the channel and advanced it 2 inches beyond the endoscope tip. The RN then cut the brush with sterile scissors and dropped it into a sterile specimen cup. The nurses inoculated a 1-mL aliquot of each well-mixed sample onto trypticase agar with 5% sheep blood, thioglycollate broth, Centers for Disease Control and Prevention anaerobic blood agar plate, and Sabouraud dextrose agar. All media were incubated at 25° C to 35° C (77° F to 95° F) for seven days.

Instrument validity and reliability. No instrument was used in this study.

Response rate. No surveys or questionnaires were used in this study, so response rate is not applicable.

Tables. The article included three tables that presented

- nonpathogens,
- potential pathogens, and
- isolates by endoscope.

The contents of the tables were consistent with the article narrative and clearly summarized the findings.

Results. The results were presented clearly. There were 33 positive cultures from 28 of the 96 sites tested for an overall contamination rate of 29.2%. Typical skin or environmental contaminants accounted for 29/33 (88%) of the microorganisms isolated, which was considered clinically insignificant. Four potential pathogens (ie, *Enterococcus*, *Candida parapsilosis*, *α-hemolytic Streptococcus*, *Aureobasidium pullulans*) were recovered from the biopsy channels in two colonoscopes, and one pathogen was recovered at one site and time point from one duodenoscope and one gastroscope at only one site and time point. All grew in low concentrations well below the proposed threshold of 100 colony forming units/mL.

Result-based conclusions. The researchers found that endoscopes can be stored for as long as 21 days after reprocessing using high-level disinfection techniques with a low risk of microbial contamination. They concluded that flexible endoscopes can be stored safely after standard high-level disinfection procedures for longer periods than the five to seven days that is current practice in many units. However, they note that the maximum duration that the reprocessed endoscopes may be stored is unknown.

Study limitations. The researchers did not identify any limitations. However, the researchers noted that they elected to sample the endoscope channels as opposed to the surface because previous studies have indicated that the channels are the best means of assessing microbial colonization because they are more likely to harbor microorganisms than the surface of the scope.

Quality of evidence. When using the AORN Research Evidence Appraisal Tool, this study was classified as B for quality of evidence because the authors provided a fairly robust and current literature review and presented a fairly definitive conclusion that reprocessed endoscopes can be stored for longer periods than what is currently practiced.

APPRAISAL RESULTS

The AORN Research Evidence Appraisal Tool was used to score this study as III B.

- The study was scored as III for level of evidence because it was a nonexperimental, prospective, observational study and had no manipulation of independent variables and no controls.
- The study scored as B for quality of evidence. The literature review was current and robust, and the fairly definitive conclusion that reprocessed endoscopes can be stored for longer periods than is currently practiced was reached.
- A score of III B indicates that it may be appropriate for perioperative nurses to consider this evidence as a secondary source of evidence when designing policies and procedures for the perioperative setting provided that it supports other primary sources of evidence. Studies of lesser strength or quality are not necessarily inferior or unacceptable sources of evidence, and a lower rating does not necessarily mean the evidence is unimportant or irrelevant.

PERIOPERATIVE IMPLICATIONS

The results of this study revealed that flexible endoscopes can be stored for as long as 21 days after reprocessing with a low risk of pathogenic microbial colonization. The researchers pointed out that the maximum duration that reprocessed endoscopes can be stored safely is unknown and that further studies with extended cultures beyond 21 days are needed. Increasing the storage time from five to seven days to 21 days may represent a substantial cost savings, so perioperative nurses and managers should consider this evidence when they are developing or updating their policies and procedures for storage of reprocessed endoscopes. Additionally, given that the maximum shelf life is unknown, perioperative nurses should participate in designing and conducting additional studies to determine the maximum time reprocessed endoscopes can be stored before contamination occurs. ●

This article was appraised by George Allen, PhD, MS, BSN, RN, CNOR, CIC, director of infection control, Downstate Medical Center, and clinical assistant professor, SUNY College of Health Related Professions, Brooklyn, NY. *Dr Allen has no declared affiliation that could be perceived as posing a potential conflict of interest in the publication of this article.*