The length of time that flexible endoscopes which have undergone reprocessing with high-level disinfection can safely be stored before use: a systematic review protocol

Marilee Schmelzer PhD, RN[1,4]

Glenda Daniels PhD, RN[2,4]

Helen Hough MLS[3]

1 Retired from the University of Texas, Arlington, Texas, USA

2 Texas Christian University, Fort Worth, Texas, USA

3 University of Texas, Arlington, USA

4. Texas Christian University Center for Evidence Based Practice and Research: a collaborating centre of the Joanna Briggs Institute

Corresponding author

Marilee Schmelzer

schmelze@uta.edu

Review question/objective

How long (in days) do flexible endoscopes that have undergone reprocessing with high-level disinfection (HLD) maintain the same level of disinfection and remain safe to use when stored as recommended by the manufacturer?

The objective of this review is to systematically review the best available evidence related to the safe hang time or storage time (in days) of flexible endoscopes that have undergone reprocessing with high-level disinfection in order to determine when they can be safely used without posing any risk of contamination from pathogens.

Background

Endoscope definition and use

Endoscopes are used worldwide to screen for colon cancer and provide diagnostic information for gastrointestinal (GI) and pulmonary conditions, as well as for therapeutic interventions (e.g. removing biliary tract stones, removing polyps, cauterizing blood vessels in bleeding ulcers) and for surveillance purposes. An estimated 55 million endoscopies were performed in the United States in 2009 and 50% were for colonoscopies.[1] The exact number of endoscopic procedures performed worldwide is unknown. However, endoscopy is commonly used for early detection of three of the 20 leading causes of death worldwide.[2] These include tracheal, bronchial and lung cancer (eighth leading cause at 1.3 million deaths); stomach cancer (17th at 0.8 million deaths); and colorectal cancer (20th at 0.6 million

deaths). Endoscopy is also used to diagnose conditions such as peptic ulcer disease, inflammatory bowel disease, irritable bowel syndrome, celiac disease, diverticulosis, gastro-esophageal reflux disease and other digestive diseases which may not have such high mortality rates, but still cause significant morbidity and loss of productivity.

Endoscopes are mechanical instruments that are inserted through a natural orifice in the body in order to look directly at the internal organs.[3] They can be inserted through the mouth or anus in order to look directly at the walls of the gastrointestinal tract (Figure 1). A specific endoscope, the bronchoscope, is inserted through the mouth or the nose in order to view the trachea and passageways to the lungs. The first endoscopes were very rigid, but innovations in technology have produced a more flexible instrument. Current endoscopes are flexible, have fiber-optics to provide light and moveable parts that can be threaded around angles in the GI tract. The most advanced endoscopes now utilize computer technology to provide enhanced imagery, video recordings and final reports. The endoscope essentially has a camera attached to a long, thin tube which moves through the openings in the body and projects the images onto an external screen. The endoscope can be used to look at the trachea, bronchi and lungs (bronchoscopy); colon (colonoscopy and sigmoidoscopy); esophagus and stomach (upper gastrointestinal endoscopy); and biliary tract (endoscopic retrograde pancreatography).

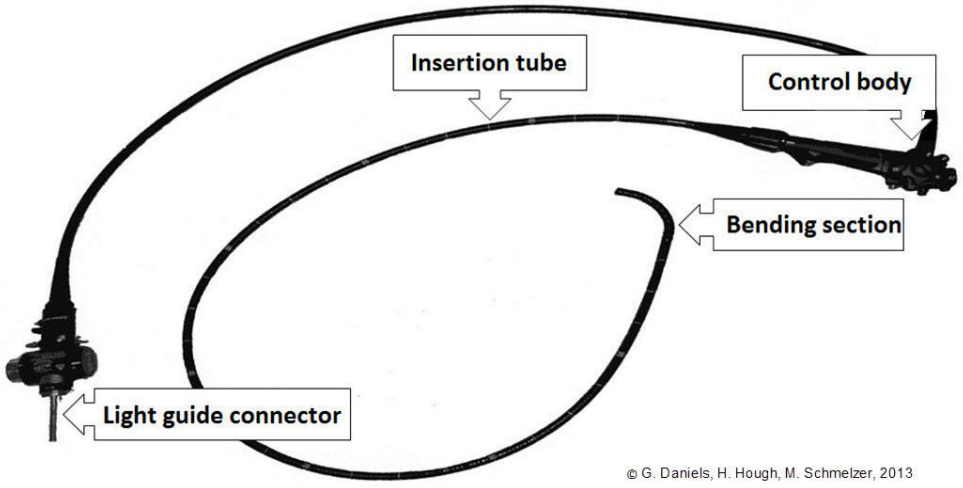


Figure 1: Parts of the Flexible Endoscope

The flexible endoscope is a complex instrument with delicate parts which break or malfunction unless the endoscope is handled appropriately. As seen in Figure 1, the endoscope has four major parts: the control body, the insertion tube, the bending section (distal tip) and the light guide connector. The internal components of the endoscope include: (a) a mechanical system which permits the tip to be manipulated in different directions; (b) a plumbing system with suctioning to remove gas, secretions, irrigants and other fluids; and (c) an illumination system which allows the inside of the body to be seen on a monitor. The endoscope also has removal accessories which include valves and caps.[4]

Endoscopes are inserted through the upper respiratory tract or the gastrointestinal tract, which contain colonies of microorganisms (e.g. bacteria, viruses). Therefore, a used endoscope must be appropriately

cleaned and reprocessed to remove all microorganisms in order to avoid infecting subsequent patients. Reprocessing is a standardized process of pre-cleaning, leak testing, manual cleaning, rinse after cleaning, high-level disinfection (manual or with automated reprocessors), rinsing to remove high-level disinfectants, drying and storage. Strict adherence to reprocessing guidelines effectively removes all microorganisms and most spores from contaminated endoscopes, without damaging the scopes. Although sterilization is more effective at killing microorganisms and spores, it cannot be used because it damages the scopes.

Need for and nature of reprocessing

Proper reprocessing of endoscopes and accessories is critical to the safe and successful treatment of patients.[5] The Society of Gastroenterology Nurses and Associates (SGNA),[3] the American Society for Gastrointestinal Endoscopy (ASGE),[5] and the European Society of Gastrointestinal Endoscopy,[6] support increased research in the areas of endoscope design. They encourage manufacturers to develop flexible gastrointestinal endoscopes that are easily disassembled for reprocessing and verifying the effectiveness of both cleaning and high-level disinfection.

Flexible endoscopes reprocessed according to national and international standards pose virtually no risk of transmission of patient-borne or environmental microorganisms when scopes are used soon after being reprocessed.[3] Endoscopes which are not reprocessed following these standards may develop biofilm, a matrix of different types of bacteria that adhere to the endoscopes and are resistant to high-level disinfection.[7,8] Failure to adhere to established reprocessing guidelines, defective endoscopes and automated reprocessors, and contaminated water sources account for all of the reported cases of bacterial and viral transmissions.[5] In the absence of defective equipment, every reported case of hospital acquired infection associated with a contaminated endoscope has been linked to a breach in the requisite reprocessing steps.[5]

The Spaulding classification system is universally used to choose the appropriate method of disinfection or sterilization for a particular class of medical device.[5] Medical devices are classified as critical, semi-critical or non-critical, depending on how the device is used. Critical devices (e.g. reusable biopsy forceps) break the mucosal barrier and should be sterilized. Semi-critical devices (e.g. endoscopes) come in contact with mucous membranes or non-intact skin and should be sterilized or receive high-level disinfection. Non-critical devices (e.g. blood pressure cuffs and stethoscopes) touch intact skin and can be cleaned with soap and water or disinfected with a germicide.

Steps in endoscope reprocessing (including high-level disinfection)

As a semi-critical device, endoscope reprocessing includes cleaning, high-level disinfection, high-level rinsing and drying.[5,9]

1. Cleaning. Cleaning includes pre-cleaning, leak testing and manual cleaning and rinsing. First, the endoscope is immediately pre-cleaned after use in order to remove gross contamination before it can adhere and harden. Prompt efficient cleaning helps to prevent biofilm, a matrix of microorganisms and other debris that form on the endoscope surfaces and are resistant to high-level disinfection. After removing the detachable parts, the endoscope is tested for leaks in order to determine whether it can be safely reprocessed. After leak testing, the endoscope is mechanically cleaned with brushes, detergents and rinses. All interior channels are cleaned with a low foaming enzymatic detergent and brushes. The scope is thoroughly rinsed with water after cleaning to remove all detergent and debris.

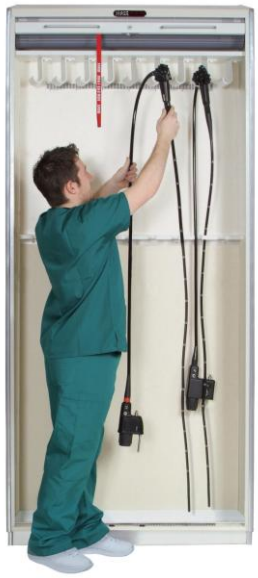
2. Disinfecting. Once an endoscope has been properly cleaned, it must be immersed in an approved high-level disinfectant to kill microorganisms. A high-level disinfectant is a type of germicide that is used only on inanimate objects because it damages human tissue. High-level disinfectants destroy all viruses, vegetative bacteria, fungi, mycobacterium and most, but not all, bacterial spores.[9]

The endoscopes are placed in approved basins that allow full immersion in the disinfectant and remain immersed for the length of time recommended by the manufacturer. Although high-level disinfection can be done manually, most American endoscopy units use automated endoscope reprocessors which can be programmed to provide the proper immersion and contact time. The use of non-immersible endoscopes is no longer acceptable because endoscopes that cannot be completely immersed in liquid cannot be adequately cleaned and disinfected.[10]

3. Rinsing. Immediately after disinfection, the scope is rinsed with sterile, filtered or tap water that meets clean water standards. Thorough rinsing is essential to remove all traces of disinfectant which is toxic to body tissues. If there is any possibility that the water used for rinsing could reintroduce microorganisms into the scope, sterile water should be used. The World Gastroenterology Organisation recommends boiled water when other sources of safe water are unavailable.[11]

4. Drying. The final step in the process is drying of the endoscope. Alcohol is often utilized followed by forced air through the channels to completely dry the entire endoscope prior to storage. Alcohol is not used in all countries because of its fixative properties or when reprocessed scopes will not be subjected to overnight or longer storage.[6]

Used with permission from
Logiquip Healthcare Storage Solution
www.logiquip.com



Used with permission from
MASS Medical Storage
www.massmedicalstorage.com

Figure 2: Example of endoscope storage

5. Storage. Endoscopes are stored (with detachable parts removed) in cabinets that allow them to hang freely in order to prevent the accumulation of moisture, a medium for growth of microorganisms (Figure 2). The endoscopes should be hung vertically and steps should be taken to avoid their **recontamination**. The storage area must be clean, dust free and well ventilated so that the scopes remain clean and dry. Examples of recontamination of an endoscope while in storage include incidental touching, dust, or airborne contaminants. Inadequate endoscope drying and improper storage have been linked to pseudomonas aeruginosa transmission.

Motivation for the review

The literature reveals a lack of clarity about the length of time endoscopes may be stored before they pose a contamination risk. For example, the document, Guideline for Disinfection and Sterilization in Healthcare Facilities, from the Centers for Disease Control provides detailed steps for reprocessing endoscopes, but makes no recommendations about the length of time scopes can be safely stored before reuse.[9] The Multisociety Guideline for Reprocessing Flexible Gastrointestinal Endoscopes concludes that "although reuse of endoscopes within 10 to 14 days of high-level disinfection appears to be safe, data are insufficient to provide a maximal duration for use of appropriately cleaned, reprocessed, dried, and stored flexible endoscopes".[5(p1080)] Infection control guidelines from the Gastroenterological Society of Australia limits storage to 12 to 72 hours before reprocessing, depending on the type of scope.[12] Other organizations, including the Society of Gastroenterology Nursing and Associates, make no recommendations because of the lack of scientific evidence.[3] The European Society of Gastrointestinal Endoscopy and the European Society of Gastroenterology and Endoscopy Nurses and Associates leave the endoscope storage decision to local policies.[6]

Three studies identified in an initial search of the literature on safe storage of endoscopes, varying amounts of safe shelf life following endoscope reprocessing ranging from five days,[13] to seven days.[14,15] The length of shelf life was limited by the time span of the study. When discussing length of storage, these studies assumed that the endoscopes were properly reprocessed (including thorough drying) and stored appropriately (no caps or valves attached, hung vertically in a clean, well-ventilated cabinet, with recommended temperature and humidity levels).[16] In all three studies, the outcome, endoscope contamination, was measured by flushing endoscope channels with sterile water at various time periods and culturing the returns to determine whether microorganisms were present.[13-15]

Endoscopy is used around the world to diagnose and treat gastrointestinal and pulmonary diseases. Since the endoscopes are contaminated during use, proper cleaning and disinfection are necessary to prevent the spread of disease. Contaminated endoscopes have been linked to such prevalent diseases as hepatitis C, hepatitis B and helicobacter pylori, which are particularly common in developing countries.[17] Researchers around the world have established the effectiveness and safety of endoscope reprocessing practices for preventing the transmission of infection, but shelf life/hang time has received little attention.[11,18-21] It is not known how long endoscopes can be safely stored; therefore, some facilities reprocess them every morning even if they were reprocessed the day before. Daily reprocessing of unused scopes is costly, time consuming and may be unnecessary. Excessive reprocessing also increases the amount of used high-level disinfectants which are environmental contaminants and therefore require special disposal practices.[22,23] Knowing how long reprocessed endoscopes can be safely stored is essential for preventing infection and decreasing unnecessary costs. Whilst there are at

least a handful of studies examining the issue of how long endoscopes may be safely stored, a search of the leading medical databases including MEDLINE, CINAHL and EMBASE revealed that no systematic review has been conducted over the last three years on the topic, or is in progress.

Keywords

contamination; endoscope; high-level disinfection; reprocessing; storage

Inclusion criteria

Types of participants

This systematic review does not aim to identify and include studies that have involved human participants, but rather that have included high-level disinfected endoscopes that are not immediately used. The review's approach with respect to the type of endoscope is inclusive and with the exception of one kind, studies that have focused on use, reprocessing and storage hang time of any type of endoscope (e.g. gastroscope, bronchoscope, jejunoscope, laryngoscope, colonoscope, etc.) are to be considered for inclusion. The exception endoscope, that will not be considered, is the natural orifice translumenal endoscopy (NOTES). This is because NOTES is an emerging technology where a surgical procedure is performed to gain access to an organ (e.g. kidney, gall bladder) through a natural orifice.[24]

To be considered for inclusion, the endoscopes must have been cleaned using the recommended reprocessing steps described previously. In addition, the studies must have included reports of negative or positive culture of microorganisms and the specific length of time that cultures were obtained following reprocessing.

Phenomena of interest

The phenomena of interest of the proposed review is the length of time that endoscopes which have been properly reprocessed and stored can remain in a storage cabinet or closet before reuse without presenting a contamination risk.

Types of outcomes

This review will consider studies that include the following outcome measures: length of endoscope storage and measure of microorganism growth (e.g. cultures). The studies must also include the type of endoscopes used, as well as the method used to contaminate the endoscopes and specific reprocessing steps (e.g. type of rinse water, specific high level disinfectant, manual or automated reprocessing, method of drying before storage).

Types of studies

This review will consider both experimental and epidemiological study designs including randomized controlled trials, non-randomized controlled trials, quasi-experimental, before and after studies, prospective and retrospective cohort studies. Studies involving microbiological testing of the endoscope immediately following HLD and ongoing microbiological surveillance will be needed and included.

Search strategy

The initial search will not be limited by language, but only studies in English and Spanish will be reviewed since the reviewers are native English speakers, speak some Spanish and have ready access to a certified Spanish-English translator. The search strategy will identify both published and unpublished studies. A three-step search strategy will be used in this review. First, a search of MEDLINE, CINAHL and EMBASE will be undertaken, followed by analysis of the text words contained in the title and abstract and of the index terms used to describe the articles. These include endoscope, reprocessing, shelf life and hang time. Second, a search using all identified keywords and index terms will be undertaken across all included databases. Third, the reference lists of all identified reports and articles will be searched for additional studies. Pertinent references will also be used for a citation search (to find others who have cited the references) to find more current materials.

The databases to be searched include:

• MEDLINE

• ProQuest Dissertation (includes unpublished dissertations)

• EMBASE

• CINAHL

• Google Scholar (includes unpublished studies and “Cited by” function)

• Publications of the American Chemical Society

• Biological Abstracts

• Thompson’s World of Science (citation database)

Studies identified in these databases will be considered for inclusion in this review. The inclusion dates for consideration in this review will be 1990 – to date, since high-level disinfection of immersible endoscopes was not standardized until after 1991.[25] Since studies published since 1990 are being reviewed, it is expected that all publications will be available electronically and therefore a hand search will be unnecessary.

Initial keywords to be used will be:

• High-level disinfection

• Contamination

• Disinfection

• Hang time

• Shelf life

• Storage

• Sterilization

• Endoscopes (bronchoscope, gastroscope, colonoscope, jejunoscope)

• Microorganisms

• Reprocessing

The titles for all studies identified during the database search will be checked to eliminate duplicates. Each study will be assessed for relevance using information from the title, abstract and descriptor/MeSH terms. The full text will be retrieved for any study that is determined to be relevant and meets inclusion criteria. Studies identified from reference list searches will be assessed for relevance based on the study title and if deemed relevant, the full texts will be retrieved.

When reviewing the full reports of studies, a checklist (Appendix I) will be used to determine whether or not each study meets inclusion criteria.

Assessment of methodological quality

Papers selected for retrieval will be assessed by two independent reviewers for methodological validity prior to inclusion in the review using standardized critical appraisal instruments from the Joanna Briggs Institute Meta-Analysis of Statistics Assessment and Review Instrument (JBI-MAStARI) (Appendix II). Any disagreements that arise between the reviewers will be resolved through discussion, or with a third reviewer.

Data collection

Data will be extracted from papers included in the review using the standardized data extraction tools from JBI-MAStARI (Appendix II). The data extracted will include specific details about the interventions, populations, study methods and outcomes of significance to the review question and specific objectives. The reviewers will attempt to contact the authors of primary studies when information is missing or unclear.

Data synthesis

Quantitative data will, where possible, be pooled in statistical meta-analysis using JBI-MAStARI. All results will be subject to double data entry. Effect sizes expressed as odds ratios (for categorical data) and weighted mean differences (for continuous data) and their 95% confidence intervals will be calculated for analysis of storage time and microorganism colonization. Heterogeneity will be assessed statistically using the standard Chi-square and also explored using subgroup analyses based on the different study designs included in this review. Where statistical pooling is not possible, the findings will be presented in narrative form including tables and figures to aid in data presentation where appropriate.

Conflicts of interest

There is no conflict of interest for any of the reviewers.

Acknowledgements

The Society of Gastroenterology Nurses and Associates (SGNA) is dedicated to developing a repository of data utilizing best evidence to enhance outcomes in the gastrointestinal setting. The primary and secondary reviewers are SGNA scholars and appreciate the support of the SGNA. The third reviewer is a health science librarian at the University of Texas at Arlington. The reviewers

acknowledge The University of Texas at Arlington and Texas Christian University for ongoing support of scholarly activities.

References

1. Fields R. 35 statistics about GI/endoscopy. 2010 September. Available from http://www.beckersasc.com/gastroenterology-and-endoscopy/35-statistics-about-giendoscopy-in-ascs.html.
2. World Health Organization. The global burden of disease: 2004. Geneva, Switzerland: WHO Press; 2008.
3. SGNA [Society of Gastroenterology Nurses and Associates, Inc.]. Standards of infection control in reprocessing of flexible gastrointestinal endoscopes. 2012. Available from http://www.sgna.org .
4. Study Guide: The care and handling of flexible endoscopes. STERIS Corporation. 2012. Available from: https://steris.sabanow.net.
5. American Society of Gastrointestinal Endoscopy Multisociety guideline on reprocessing flexible gastrointestinal endoscopes: 2011. Gastrointestinal Endoscopy. 2011. 73(6):1075-1084, doi:10.1016/j-gie.2011.03.1183.
6. Beilenhoff U, Neumann CS, Rey JF, Blering H, Blum R, Climbro M, Kampf B, Rogers M, Schmidt V. ESGE-ESGENA guideline: Cleaning and disinfection in gastrointestinal endoscopy update 2008. Endoscopy. 2008. 40:939-957 doi: 10.1055/s-2008-1077722.
7. Association for the Advancement of Medical Instrumentation. Chemical sterilization and high-level disinfection in health care facilities. ANSI/AAMI ST58:2005/(R) 2010. Arlington, VA: Author.
8. Miner N, Harris V, Ebron T, Cao T. Sporicidal activity of disinfectants as one possible cause for bacteria in patient ready endoscopes. Gastroenterology Nursing. 2007. *30*(4):285-290 doi: 10.1097/01.sga.0000287201.98483.43.
9. Rutala WA, Weber DJ. The Healthcare Infection Control Practices Advisory Committee. Guideline for disinfection and sterilization in healthcare facilities. 2008. Available from http://www.cdc.gov/hicpac/Disinfection/_Sterilization/17_00Recommendations.html.
10. Rutala WA, Weber DJ. Disinfection and sterilization in health care facilities: What clinicians need to know. Clinics in Infectious Diseases. 2004. 39:702-709 doi: 10.1086/423182.
11. World Gastroenterology Organisation. Endoscope disinfection a resource-sensitive approach. World Gastroenterology Organisation/WEO Global Guideline. 2011. 1-12.
12. GESA (Gastroenterological Society of Australia) & GENCA (Gastroenterological Nurses College of Australia). Clinical update: Infection control in endoscopy. Gastroenterological Society of Australia 2010.
13. Osborne S, Reynolds S, George N, Lindemayer F, Gill A, Chalmers M. Challenging endoscopy reprocessing guidelines: A prospective study investigating the safe shelf life of flexible endoscopes in a tertiary gastroenterology unit. Endoscopy. 2007. 39:825-830 doi: 10.1055/s-2007-966766.
14. Riley R, Beanland C, Bos H. Establishing the shelf life of flexible colonoscopes. Gastroenterology Nursing. 2002. 25(3):114-119 doi: 10.1097/00001610-200205000-00006.
15. Vergis AS, Thomson D, Pieroni P, Dhalla S. Reprocessing flexible gastrointestinal endoscopes after a period of disuse: Is it necessary? Endoscopy. 2007. 39:737-739 doi: 10.1055/s-2007-966644.
16. Catalone B, Drosnock M. Storing endoscopes: How long is too long? Scientific exploration casts doubt on sacred cow traditions. Healthcare Purchasing News. 2010. Available from http://www.hpnonline.com/inside/2010-11/1011-endo-storage.html.
17. Nelson DB, Muscarella L. Current issues in endoscope reprocessing and infection control during gastrointestinal endoscopy. World Journal of Gastroenterology. 2006. 12(25):3953-3964.
18. Chiu KW, Fong TV, Wu K, Chiu YC, Chou YP, Kuo CM et al. Surveillance culture of endoscope to monitor the quality of high-level disinfection of gastrointestinal reprocessing. Hepato-Gastroenterology. 2010. 57:531-534 doi: 10.1186/1471-230x-12-120.
19. Crawford A. Decontamination and traceability of flexible endoscopes. Journal of Perioperative Practice. 2007. 17:257-264.
20. Seoane-Vazquez E, Rodriguez-Mongulo R, Visarta J, Carlson A. Endoscopy-related infections and toxic reactions: An international comparison. Endoscopy. 2006; 39:742-746 doi: 10.1055/s-2007-966504.
21. Soares JB, Goncalves R, Banhudo A, Peddrosa J. Reprocessing practice in digestive endoscopy units of district hospitals: Results of a Portuguese national survey. European Journal of Gastroenterology & Hepatology. 2011. 23(11):1064-1068 doi: 10.1097/meg.0b013e328348d5d6.

22. Government of South Australia. Glutaraldehyde and ortho-phthaladehyde (OPA) disinfectant disposal to sewer: Trade waste guideline. 2013 January. Available from http://www.sawater.com.au/NR/rdonlyres/AC69D992-69BF-439E-B853-7D6BD19EB691/0/GlutaraldehydeandOPAdisposal.pdf.
23. National Center for Manufacturing Sciences. Sterilants and disinfectants in healthcare facilities n.d. Available from http://www.hercenter.org/hazmat/steril.cfm
24. Natural Orifice Surgery Consortium for Assessment and Research. About NOSCAR 2013. Available from http://www.noscar.org/about-noscar/.
25. Rutala WA, Clontz EP, Weber DJ, Hoffmann KK. Disinfection practices for endoscopes and other semicritical items. Infection Control and Hospital Epidemiology: the Official Journal of the Society of Hospital Epidemiologists of America. 1991. 12(5):282-8 doi: 10.1086/646340.

Appendix I: Evidence from studies checklist

Authors Year country	Methods	Followed standard reprocessing guidelines	Type of Endo-scopes	HLD Type	Manual or AER	Type of rinse water	Drying method	Storage site description	Length of storage	Micro-Bio-logical testing	Organism identified	Recommen-dations

Appendix II: Appraisal instruments

MAStARI appraisal instruments

JBI Critical Appraisal Checklist for Randomised Control / Pseudo-randomised Trial

Reviewer _____ Date _____

Author _____ Year _____ Record Number _____

	Yes	No	Unclear	Not Applicable
1. Was the assignment to treatment groups truly random?	☐	☐	☐	☐
2. Were participants blinded to treatment allocation?	☐	☐	☐	☐
3. Was allocation to treatment groups concealed from the allocator?	☐	☐	☐	☐
4. Were the outcomes of people who withdrew described and included in the analysis?	☐	☐	☐	☐
5. Were those assessing outcomes blind to the treatment allocation?	☐	☐	☐	☐
6. Were the control and treatment groups comparable at entry?	☐	☐	☐	☐
7. Were groups treated identically other than for the named interventions	☐	☐	☐	☐
8. Were outcomes measured in the same way for all groups?	☐	☐	☐	☐
9. Were outcomes measured in a reliable way?	☐	☐	☐	☐
10. Was appropriate statistical analysis used?	☐	☐	☐	☐
	☐	☐	☐	☐

Overall appraisal: Include ☐ Exclude ☐ Seek further info. ☐

Comments (Including reason for exclusion)

_____

_____

_____

JBI Critical Appraisal Checklist for Descriptive / Case Series

Reviewer _____ Date _____

Author _____ Year _____ Record Number _____

	Yes	No	Unclear	Not Applicable
1. Was study based on a random or pseudo-random sample?	☐	☐	☐	☐
2. Were the criteria for inclusion in the sample clearly defined?	☐	☐	☐	☐
3. Were confounding factors identified and strategies to deal with them stated?	☐	☐	☐	☐
4. Were outcomes assessed using objective criteria?	☐	☐	☐	☐
5. If comparisons are being made, was there sufficient descriptions of the groups?	☐	☐	☐	☐
6. Was follow up carried out over a sufficient time period?	☐	☐	☐	☐
7. Were the outcomes of people who withdrew described and included in the analysis?	☐	☐	☐	☐
8. Were outcomes measured in a reliable way?	☐	☐	☐	☐
9. Was appropriate statistical analysis used?	☐	☐	☐	☐

Overall appraisal: Include ☐ Exclude ☐ Seek further info ☐

Comments (Including reason for exclusion)

JBI Critical Appraisal Checklist for Comparable Cohort/ Case Control

Reviewer _____ Date _____

Author _____ Year _____ Record Number _____

	Yes	No	Unclear	Not Applicable
1. Is sample representative of patients in the population as a whole?	☐	☐	☐	☐
2. Are the patients at a similar point in the course of their condition/illness?	☐	☐	☐	☐
3. Has bias been minimised in relation to selection of cases and of controls?	☐	☐	☐	☐
4. Are confounding factors identified and strategies to deal with them stated?	☐	☐	☐	☐
5. Are outcomes assessed using objective criteria?	☐	☐	☐	☐
6. Was follow up carried out over a sufficient time period?	☐	☐	☐	☐
7. Were the outcomes of people who withdrew described and included in the analysis?	☐	☐	☐	☐
8. Were outcomes measured in a reliable way?	☐	☐	☐	☐
9. Was appropriate statistical analysis used?	☐	☐	☐	☐

Overall appraisal: Include ☐ Exclude ☐ Seek further info. ☐

Comments (Including reason for exclusion)

Appendix II: Data extraction instruments

MAStARI data extraction instrument

JBI Data Extraction Form for Experimental / Observational Studies

Reviewer _____ Date _____

Author _____ Year _____

Journal _____ Record Number _____

Study Method

RCT ☐ Quasi-RCT ☐ Longitudinal ☐

Retrospective ☐ Observational ☐ Other ☐

Participants

Setting

Population

Sample size

Group A _____ Group B _____

Interventions

Intervention A

Intervention B

Authors Conclusions:

Reviewers Conclusions:

Study results

Dichotomous data

Outcome	Intervention ( ) number / total number	Intervention ( ) number / total number

Continuous data

Outcome	Intervention ( ) number / total number	Intervention ( ) number / total number