WELCOME TO THIS NEWSLETTER'S 5TH YEAR OF PUBLICATION

The Q-Net™ Monthly

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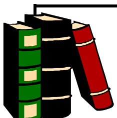
WELCOME

Welcome to The Q-Net™ Monthly's 5th year of publication. On occasion, a double issue of this newsletter will be published, as some topics cannot be adequately discussed in a single issue's two page layout.

If you have a question you would like addressed in this newsletter, please send it to the editor. This newsletter encourages discussions of recent epidemiological investigations that have unearthed potential sources of patient infection.

Q-Net '98



'Q-Net-98' is now available. This book contains all of the past year's newsletters in a bound booklet. Order your copy today. $9.95 includes S&H.

What is 'Q-Net'?

Q-Net is a technology-assessment network of questions and answers. Its newsletter is The Q-Net™ Monthly.

Q-Net's main goal is to encourage the infection control and endoscopy communities not only to ask good questions but also to demand succinct and well referenced responses.

Q-Net addresses the needs of both the health care provider whose goal is to provide the best care possible, and the patient who deserves affordable quality health care.

Ultrasonic cleaning

This article is based on a more detailed discussion of ultrasonic cleaning, written by this newsletter's editor, that will appear in "Surgical Services Management" later this Spring.

Introduction

Recent technological advances have hastened growth in the field of infection control and instrument reprocessing. Reports of the transmission of bloodborne pathogens by surgical equipment *(refer to the November 1997 issue of this newsletter)* have increased the demand for the development and utilization of cost-effective reprocessing methods that prevent cross-infection.

As important as improving the effectiveness and reliability of processes that achieve sterilization (and disinfection) is developing automated technologies that can clean even the most complex instruments. Unless the instrument is thoroughly cleaned, the sterilization process is likely to fail.

To be sure, the number of surgical procedures that use minimally-invasive instruments continues to increase. In addition to reducing the "invasiveness" of the procedure, these instruments benefit the patient on many fronts, including a reduction in patient morbidity, hospital-stay, and the surgical procedure's costs, to name only a few.

But minimally-invasive instruments are often complex and rarely are designed to facilitate cleaning.[1] Many of them require extra training and time for reprocessing staff to learn and perform the unique reprocessing steps that they require. Dovetailing more effectively the cleaning process with the internal designs of these complex and often delicate instruments is essential to prevent disease transmission.

What is ultrasonic energy?

Ultrasonic energy is one of the most popular and universally-accepted technologies for cleaning instruments. It has been used for many years both in industry and health care facilities, providing the standard to which other cleaning methods are often compared.[2]

Ultrasonic cleaners use high-intensity sound waves, produced by electrically-powered transducers, to clean soiled instruments. Unlike audible sound waves traveling through air, ultrasonic sound waves are inaudible, usually traveling at frequencies between 20 and 120 kHz (1 kHz equals 1000 Hz, or oscillations per second). Moreover, ultrasonic waves require a liquid medium (instead of air) for their efficient transmission.

As the ultrasonic waves travel through the liquid medium, which is typically a cleaning solution, their energy causes millions of microscopically-sized cavities, or bubbles, to form through a

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process known as cavitation. These tiny cavities reach a critical threshold and violently collapse, or implode, creating submicroscopic voids in the cleaning solution.

Not only does cavitation create a powerful suction-effect that purges adhering soil, microorganisms and other debris from even the most inaccessible surfaces of an instrument,[3] but cavitation also creates high-energy hydraulic shock waves that may reach temperatures as high as 10,000 ^{0}F and pressures as low as -10,000 pounds-per-square inch (PSI).[4] These shock waves clean instruments by loosening and removing adhering debris.[5]

Why use an ultrasonic cleaner?

In addition to its industrial applications,[6] ultrasonic energy is routinely used by health care facilities to clean surgical and dental instruments. Not only do they standardize the cleaning process, but ultrasonic cleaners can also:

- increase employee productivity by reducing the time required to manually scrub soiled instruments;[3] and
- reduce liability by minimizing the handling of, and employee exposure to, sharp instruments that may be contaminated with bloodborne pathogens.[3,7,8]

Many studies demonstrating the reliability and cleaning effectiveness of ultrasonic energy have been published. Some report that ultrasonic cleaning is very effective in removing dried serum, whole blood, and viruses from contaminated instruments.[3,7,9] Published data also indicate that ultrasonic cleaners are significantly more effective and efficient than manual scrubbing,[7,10] a process that is difficult to standardize and can yield incomplete and inconsistent results.[9]

✓ *Ultrasonic cleaners are automated and standardized devices designed to clean inaccessible surfaces that might otherwise remain contaminated after manual scrubbing.*

While manual scrubbing prior to ultrasonic cleaning is intended to:

- remove gross and accessible debris, and
- prevent soil from drying on the instrument's surfaces,

ultrasonic cleaning is designed to further reduce the risk of cross-infection by removing less accessible debris that remains on the instrument after manual scrubbing.

Not surprising, reports suggest that ultrasonic cleaning preceded by manual scrubbing is more effective than either alone.[4] One study demonstrated that as few as three minutes of ultrasonic exposure is sufficient to remove more than 99.9% of blood on contaminated instruments.[5]

Although data demonstrating their effectiveness in the narrow lumens and channels of complex instruments is limited, ultrasonic cleaners are recommended to increase the effectiveness of cleaning surgical instruments that feature complicated joints, hinges and other internal surfaces that are difficult, if not impossible, to clean manually.[11,12]

Limitations of an ultrasonic cleaner

As with any technology, ultrasonic cleaning has its limitations, and understanding each permits its safe harnessing and effective application. Because of its aggressive cleaning action, ultrasonic energy is not indicated for all instruments. Some instruments are fragile and may be constructed of delicate materials damaged by the power of most ultrasonic cleaners. Materials, such as quartz, silicon, alumina, and carbon steel, may erode or become etched after prolonged exposure to ultrasonic cavitation.

Erosion caused by ultrasonic energy can be minimized, if not eliminated, however, by reducing the ultrasonic cleaner's power and/or cleaning time. Review of each instrument's user manual to determine whether ultrasonic cleaning is contraindicated is recommended.

Standard features of an ultrasonic cleaner

In general, ultrasonic cleaners feature a wash phase and at least one rinse phase. They may also automatically inject detergent into the processing chamber, as well as lubricate and dry the instruments to prevent corrosion. Adapters that flush the cleaning solution through the lumens of cannulated instruments may also be featured.

Ultrasonic cleaners may have a timer and temperature control to adjust the cleaning time and temperature of the cleaning solution, respectively. They may also be equipped with settings that permit adjustment of their power (Watts) and frequency (kHz). A cover that reduces exposure of personnel and the surrounding environment to potentially harmful contaminants and aerosols during cleaning is usually standard, as are instrument trays, holders and baskets. The configuration of ultrasonic cleaners is usually for either a bench (or table) top or the floor.

Factors that affect cleaning efficacy

(A) The physical properties of the cleaning solution: Several factors can limit or enhance the effectiveness of an ultrasonic cleaner. None is as important as the physical properties of the cleaning solution (or other liquid medium), which include its temperature, viscosity, density, vapor pressure, and surface tension.

In addition to reacting chemically with soil to facilitate its removal from contaminated instruments, detergents increase cleaning effectiveness by reducing the

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water's surface tension (i.e., the resistance to movement that a surface exerts in response to a force). Reducing the surface tension of water increases cleaning effectiveness by:

- enhancing the transmission of the ultrasonic waves through a liquid medium;
- lowering the minimum amount of ultrasonic energy necessary for cavitation to occur; and
- reducing the liquid medium's resistance to flow through narrow lumens and orifices.

Detergents specifically formulated for ultrasonic cleaning, and known to be compatible with the materials of the instruments to be cleaned, are recommended to increase cleaning effectiveness.[5] Neutral or alkaline detergents are commonly used for ultrasonic cleaning.

The temperature of the cleaning solution is as important to the physics of cleaning as its surface tension. An increase in the temperature of the cleaning solution causes an increase in its vapor pressure, which enhances cavitation. Mixing the detergent with warm water is therefore recommended to improve cleaning effectiveness. Temperatures between 110^{o} F and 140^{o} F are usually indicated for water-based cleaning solutions. Of course, to avoid damaging the surgical instrument, the temperature of the cleaning solution cannot exceed the instrument's temperature parameters.

Also, because reports indicate that bacteria can proliferate in the ultrasonic cleaner's detergent solution during the course of the day,[13] using a fresh volume of water for cleaning and rinsing each new batch of soiled instruments may be advantageous to minimize personnel exposure to potentially pathogenic microorganisms.

(B) Instrument trays, holders, and baskets: The benefits of ultrasonic cleaners cannot truly be appreciated without using specially designed instrument trays, holders, baskets, or cassettes. These cleaning accessories are typically constructed of stainless steel (or other sound-reflecting material) and are often wired or meshed to permit efficient wave passage.

Each of these accessories optimizes cleaning effectiveness by:

- maximizing exposure of the soiled instruments to the ultrasonic waves; and
- preventing the instruments from contacting the bottom of the processing chamber (the other side of which the transducers are usually mounted) where they might interfere with the proper operation of the transducers and prevent transmission of the ultrasonic waves.

In addition, instrument trays, holders and baskets minimize the risk of costly damage to the soiled instruments by limiting their movement during ultrasonic cleaning.

(C) Instrument arrangement: The method by which contaminated instruments are arranged in the processing chamber can also affect cleaning effectiveness. Ultrasonic energy is *uni*-directional, traveling in only one direction from its source (the transducers) through the cleaning solution. This potential limitation can be overcome, however, by properly arranging the contaminated instruments in the processing basket (or tray) to maximize their exposure to the ultrasonic energy. Placing the contaminated instrument's most heavily soiled surface towards the bottom surface of the processing chamber (or other surface where the transducers are mounted) optimizes cleaning effectiveness.

(D) Cleaning time: The time required to clean soiled instruments depends on several factors, including:

- the design, composition, and size of the instruments;
- the number and arrangement of instruments in the processing chamber;
- the degree of instrument contamination (e.g., lightly-soiled, heavily-soiled);
- the power and frequency of the ultrasonic cleaner;
- the type, amount, temperature and effectiveness of the detergent; and
- the hardness of the water.

(E) Air bubbles: The presence of air bubbles in the cleaning solution limits cleaning effectiveness. For their efficient transmission, ultrasonic waves require a liquid medium, as they cannot travel through air. Consequently, the surfaces of instruments that are covered with air bubbles cannot be effectively cleaned by ultrasonic energy. Nor can instruments be effectively cleaned by ultrasonic energy if pockets of air remain between them.

Similarly, bubbles of air and other gases in the cleaning solution interfere with the efficient transmission of ultrasonic waves, reducing cleaning effectiveness. Once the ultrasonics are activated, however, degassing of (or, removal of the gases from) the liquid medium ordinarily occurs.

Purchasing considerations

The following list of questions may be helpful in the purchase of an ultrasonic cleaner:

- ✓ *What are the dimensions of the ultrasonic cleaner? Is the size of its processing chamber sufficient to clean the hospital's longest instruments?*
- ✓ *What types of instrument baskets, trays, or holders are standard with the purchase of the ultrasonic cleaner?*
- ✓ *What is the ultrasonic cleaner's standard cleaning time?*

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Can this time be adjusted to permit extended cleaning for big loads and heavily-soiled instruments?

- ✓ *How much power does the ultrasonic cleaner produce? Is it equipped with different power settings to permit processing of lightly- and heavily-soiled instruments, as well as delicate instruments (e.g. 450, 600, 1200 Watts)?*
- ✓ *What is the ultrasonic cleaner's frequency setting(s)?*
- ✓ *Has the ultrasonic cleaner received a 510(k) from the FDA? Is it labeled for cleaning all types of instruments, including complex instruments? If so, which ones? Does the ultrasonic cleaner's manufacturer have any validated data to support its cleaning claims?*
- ✓ *What type of detergent formulation is recommended for use in the ultrasonic cleaner? Can other detergents be used in the cleaner (without voiding its warranty)?*
- ✓ *Does the cleaner automatically inject detergent into the processing chamber? What about a lubricant?*
- ✓ *Is the cleaner equipped with a heater to increase the temperature, and enhance the effectiveness, of the cleaning solution?*
- ✓ *Does the ultrasonic cleaner use a fresh or recycled detergent solution? Does the ultrasonic cleaner rinse the instruments after cleaning? If so, how many rinse cycles does it offer? Is it fresh or recycled rinse water?*
- ✓ *Does the ultrasonic cleaner dry the instruments after cleaning? If yes, how does it dry them?*
- ✓ *Which domestic and international standards have been satisfied by the ultrasonic cleaner's manufacturer (e.g., cGMP, ISO 9001, CE Mark, EN 46001, UL)?*
- ✓ *Can the ultrasonic cleaner detect errors or safety faults? For example, can the ultrasonics be activated when the processing chamber is empty, which could result in irreversible and costly damage to the transducers?*

CONCLUSION

In addition to increasing the productivity of reprocessing staff and minimizing their exposure to contaminated instruments, ultrasonic cleaners have been shown to be more effective and efficient than manual scrubbing, which is often laborious and whose results are often incomplete and unpredictable. Other less obvious benefits of ultrasonic energy include its reported enhancement of the sporicidal properties of liquid chemical sterilants.[14]

At a time when the popularity of low-temperature sterilization processes that use chemicals is growing, placing greater emphasis and importance on optimizing the effectiveness of the cleaning process is requisite, as these chemical processes are more likely to fail than thermal sterilization processes if cleaning is inadequate.[1] The development of instrument designs that facilitate cleaning and are not damaged by the rigors of ultrasonic cavitation is recommended to reduce the risk of cross-infection.

References

1. Muscarella L.F. *AORN J* 1998 May;67(5):966-976.
2. Macdonald G. *JADA* 1996 Dec;127:17887-8.
3. Bentley EM. *Br Dent J* 1994;177:53-6.
4. Weller RN, et al. *J Endodontics* 1980 Sep;6(9):740-3.
5. Eames WB, et al. *General Dentistry* 1982 May-June;242-5.
6. Brown JS. *The Practitioner* 1998 Apr 8;232:377.
7. Carfruny WA, et al. *Am J Dent* 1995 Jun;8(3):152-6.
8. Miller CH. *JADA* 1993 Jan;124:48-56.
9. Miller CH, Hardwick LM. *General Dentistry* 1988 Jan-Feb;36:31-36.
10. Simpson JP, Whittaker DK. *Br Dent J* 1979 Feb 6; 76-8.
11. Morbidity and Mortality Weekly Report (Centers for Disease Control and Prevention). *MMWR* 1993 May 28;42(RR-8):1-12.
12. Association for the Advancement of Medical Instrumentation. Designing, testing and labeling reusable medical devices for preprocessing in health care facilities: A guide for device manufacturers. AAMI TIR No. 12, 1994.
13. Miller CH, Riggen SD, Sheldrake MA, et al. *Am J Dent* 1993 Feb;6(1):27-31.
14. Warfield DK, Bryington SQ. *Oral Surg* 1982 Apr;53 (4):342-6.

Thank you for your interest in this newsletter. *I have addressed each issue to the best of my ability. Respectfully, the Publisher: Lawrence F. Muscarella, PhD.* ***Please return completed survey to:***

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