Biofilm and Dental Unit Waterlines

In most dental settings, treatment water comes from the municipal water supply directly into the dental unit. Thin, plastic tubing carries water from the dental unit to the high-speed handpiece, air-water syringe, ultrasonic scaler, and subsequently, into the patient’s mouth. The inside surface of these dental waterlines can become colonized with a variety of microorganisms, including bacteria, fungi, and protozoa that live inside a slime layer that protects and feeds them. This phenomenon, called a biofilm, allows organisms to survive and thrive in dental waterlines. It also raises concerns about possible health effects of exposure to dental unit water.

Although biofilm forms in all water environments, the structure of narrow-bore dental tubing and the typical way dental unit water is used in the practice setting worsens the problem. Dental waterlines hold only a small amount of water, almost all of which is in contact with the inside surfaces of the tubing. This allows any microorganisms in the water to latch on to tubing walls, where they multiply to create a biofilm. Once formed, the biofilm serves as a reservoir that can increase the number of free-floating microorganisms in water used for dental treatment.

Microbial counts in dental treatment water can reach as high as 200,000 colony-forming units per milliliter (CFU/mL) within 5 days of installing new dental unit waterlines. Counts greater than 1,000,000 CFU/mL have been reported.

Although oral flora and some human pathogens have been found in dental water systems, most organisms are common water bacteria that pose little risk of illness to healthy, immunocompetent persons. Nonetheless, for health care, using water of poor quality is simply not acceptable.

No measurable risk to dental workers or patients from exposure to dental unit water has been calculated, but reasons for concern remain. Dental workers were found to have altered nasal flora or significantly higher titers of *Legionella* antibodies, suggesting exposure to the microorganism that can cause Legionnaires’ Disease. Also, contaminated dental water may have been the source of infections in the gingival tissue of two immunocompromised patients. *Pseudomonas aeruginosa*, a common water bacteria, was the cause of their infections. Furthermore, waterborne organisms have been linked to infections and disease transmission in hospitals and in the community.

Untreated or unfiltered dental unit water is likely to contain high numbers of microorganisms and is unlikely to meet drinking water standards. New infection control guidelines from the Centers for Disease Control and Prevention encourage the use of available commercial devices and products.
Biofilm and Dental Unit Waterlines

continued from front cover

procedures to improve the quality of dental treatment water. For routine, nonsurgical procedures, dental treatment water should meet standards set by the Environmental Protection Agency (EPA) for safe drinking water (that is, no more than 500 CFU/mL). During oral surgical procedures, only sterile water should be delivered to patients.

Products and protocols

A number of controls can be used to improve the quality of dental unit water. Always consult the manufacturer of your dental unit and the maker of any water-carrying devices that attach to the unit (such as ultrasonic scalers and air-polishers) for the specific products and protocols recommended. Equipment manufacturers, rather than the clinician, are charged with determining suitable, equipment-compatible ways for maintaining their units. Always follow manufacturer instructions to minimize equipment breakdown.

Self-contained water systems isolate the dental unit from the municipal supply. A bottle system affixed to the dental unit, these independent water systems allow the clinician to better control the quality of water used in dental treatment. They also provide a way to introduce biofilm- or microorganism-attacking chemicals into waterlines. Without use of a chemical agent, however, self-contained water systems do not reliably improve water quality. Improperly maintained, a contaminated bottle system can worsen the microbiological quality of dental unit water.

Used with a self-contained water system or a metering device, chemical treatments are used either periodically or continuously, depending on the specific product. While many appear to inactive or prevent biofilm in dental waterlines, the protocols may be time-consuming and technique-sensitive, and strict compliance with the manufacturer’s instructions is a must to maintain acceptable water quality. Because of the potential for equipment incompatibilities, the proper treatment protocol depends on the type and components of the dental unit.

Although they have no effect on the biofilm in the waterline, filters can produce water that meets or exceeds drinking water standards. Installation is simple, but filters must be changed according to the manufacturer-recommended schedule to maintain water quality. Chemical treatment may be necessary to address the biofilm in the supply-side of the waterlines.

Because biofilm in waterlines constantly contaminates water flowing through the lines, a standard dental unit cannot deliver sterile water to the patient, even when sterile source water is used. Sterile water delivery systems comprise a self-contained autoclavable water bottle system and disposable or autoclavable tubing. Available for oral surgery and implantology handpieces, ultrasonic scalers, and as retrofit devices for restorative handpieces, these systems can deliver sterile water to patients during oral surgical procedures. A sterile disposable irrigating syringe or a bulb syringe is a suitable alternative for delivering sterile water during oral surgical procedures.

The regulatory conundrum

Since 1996, regulatory jurisdiction for dental waterline products has been split between the Food and Drug Administration (FDA) and the EPA. Devices that attach to the dental unit must be cleared by the FDA; EPA is charged with registering germicides used in dental waterlines. Products that have both a device and germicidal component are jointly regulated.

Because EPA has yet to develop a standardized test for biofilm chemicals, no waterline product currently available has an EPA registration number. These products are legally sold as waterline “cleaners.” When selecting a waterline product for use in your practice, do your best to ensure that it has been properly evaluated for safety and effectiveness.

Follow the advice of the dental unit manufacturer on the type and frequency of biofilm-control protocol for your dental unit.

For devices that attach to waterlines, ask the manufacturer for its $10(k) number.

For chemicals used to remove or manage biofilm, ask to see independent research.
Compliance Corner

ADA Speaking to the dental industry and research community, the 1995 American Dental Association Statement on Dental Unit Waterlines calls for “improve[ing] the design of dental equipment so that ... water delivered to patients during nonsurgical dental procedures consistently contains no more than 200 CFU/mL of aerobic mesophilic heterotrophic bacteria at any point in time in the unfiltered output of the dental unit.”

CDC The Centers for Disease Control and Prevention’s “Guidelines for Infection Control in Dental Health-Care Settings, 2003” recommends that clinicians “use water that meets EPA regulatory standards for drinking water (i.e., ≤ 500 CFU/mL of heterotrophic water bacteria) for routine dental treatment output water.” For oral surgical procedures, the guidelines state, “Use sterile saline or sterile water as a coolant/irrigant when performing oral surgical procedures. Use devices specifically designed for delivering sterile irrigating fluids (e.g., bulb syringe, single-use disposable products, and sterilizable tubing).”

EPA Per the Environmental Protection Agency’s March 1999 “Guidelines for Dental Uses,” “Addition of an antimicrobial substance to a dental line on a continuous basis to keep the line clean of bacteria [requires an] FDA 510(k) and EPA registration of [the] antimicrobial product. ... Impregnation of a substance into a dental line for bacterial control [requires an] FDA 510(k) and EPA registration of the antimicrobial product. ... Addition of an antimicrobial substance to a dental line to clean the dental line (most likely a biofilm claim) followed by a rinse [requires] EPA registration. ... “[A] claim for control of biofilm for a dental use will require the submission of efficacy data and there are no efficacy methods available for developing this data. ... [A] protocol must be submitted which will be subjected to a full range of validation and peer review.”

FDA For devices that attach to the dental unit (e.g., water systems, filters, tubing), the Food and Drug Administration requires manufacturers to “submit to FDA a pre-market notification, commonly known as a ‘510(k),’ ... [which includes] information to substantiate that the device is ‘substantially equivalent’ to a legally marketed device that is not subject to premarket approval. A device may not be marketed pursuant to a 510(k) until the submitter receives written clearance from FDA.”

Glossary

Biofilm A complex colony of microorganisms, most notably bacteria, that forms on surfaces that are bathed in water

Colony-forming units The original cells that multiply to form visible colonies

Dental treatment water Nonsterile water used during dental treatment, such as for irrigating nonsurgical operative sites and cooling highspeed rotary instruments

Filter A device placed within the waterline to trap microscopic organisms

Flushing The act of running water through waterlines and/or the devices they support

Oral surgical procedures Incision, excision, or reflection of tissue that exposes normally sterile areas of the oral cavity, e.g., biopsy, periodontal surgery, apical surgery, implant surgery, and surgical extractions of teeth

Self-contained water system A container attached to a dental unit that holds and supplies water or other solutions to handpieces and air-water syringes, isolating the unit from the public water system

Sterile water Water in which there are no living organisms

Sterile water delivery system A device or system that uses a reservoir and single-use disposable or sterilizable tubing to bypass the dental unit and deliver to the patient water or other solutions that are completely free of microorganisms

Waterline The thin tubing that carries water from the water source (either the municipal water supply or a self-contained water system) to instruments used to treat patients

Infection Control In Practice is a resource prepared for clinicians by the Organization for Safety & Asepsis Procedures with the assistance and expertise of its member-contributors. OSAP is a nonprofit, independent organization providing information and education on infection control and occupational health and safety to dental care settings worldwide. Information in this issue has been brought to you with the help of the following individuals:

Contributor

Shannon Mills, DDS, is a past OSAP Chairman, co-editor of The OSAP Report, and Editor-in-Chief of Infection Control In Practice

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OSAP Chart & Checklist

Improving Dental Water Quality: A List of Currently Available Products

Consult the dental unit manufacturer and the maker of any water-carrying devices that attach to the unit (e.g., ultrasonic scaler, air-polisher) for specific products and protocols recommended. Manufacturers (rather than clinicians) determine appropriate, compatible devices and protocols for their units. Always follow the manufacturer’s instructions to minimize equipment breakdown.

Chemicals and Delivery Systems

Chemicals marked with a “*” were cleared by FDA before non-sterilant hospital germicides were reassigned to EPA. While some have a 510(k) clearance number, any germicidal components of products in this category are no longer regulated by FDA.

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<th>Company</th>
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<td>A-Dec Inc.</td>
<td>(800) 547-1883</td>
<td><a href="http://www.a-dec.com">www.a-dec.com</a></td>
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<td>ICX Waterline Tablets</td>
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<td>A-Dec Self-Contained Water System</td>
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<td>A-Dec Self Contained Water System Model 0.7 Lite</td>
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<td>AMPCO Dental</td>
<td>(800) 444-3145</td>
<td>ampcodental.com</td>
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<td>CCS-4 System</td>
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<td>MAK-1890/ Post Purge System</td>
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<td>MAK-1805m (Pressurized bottle system)</td>
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<td>MAK-1310 (Portable bottle for ultrasonic scaler)</td>
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<td>K023213</td>
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<td>DCI International</td>
<td>(800) 624-2793</td>
<td><a href="http://www.dcionline.com">www.dcionline.com</a></td>
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<td>Dental Operative Unit Accessories</td>
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<td>Sterilis, Inc.</td>
<td>(877) 755-7873</td>
<td><a href="http://www.sterilis.com">www.sterilis.com</a></td>
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<td>Bio-Free antimicrobial tubing and bottle</td>
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<td>PureLine (Point of entry water treatment/holding device using nanofiltration, reverse osmosis, germicide, and UV light)</td>
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<td>Filters require FDA clearance. Filters that release germicidal agents also will require EPA registration.</td>
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<td>DentaPure/MRLB Int’l Inc.</td>
<td>(800) 972-3543</td>
<td><a href="http://www.dentapure.com">www.dentapure.com</a></td>
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<td>DentaPure Filters</td>
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<td>VistaClear Irrigant Solution Concentrate (Citrus botanicals for continuous or intermittent treatment)</td>
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<td>K973765</td>
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<td>Patterson Dental</td>
<td>(800) 328-5536</td>
<td><a href="http://www.vistaclear.com">www.vistaclear.com</a></td>
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<td>Sterilex</td>
<td>(800) 511-1659</td>
<td><a href="http://www.sterilex.com">www.sterilex.com</a></td>
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<td>Sterilux Ultra Powder or Liquid (Hydrogen peroxide-based solution for periodic application)</td>
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<td>Sterilis, Inc.</td>
<td>(877) 755-7873</td>
<td><a href="http://www.sterilis.com">www.sterilis.com</a></td>
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<td>PureTube (Resin filter for junction box or water reservoir with continuous-release ionized-silver disinfectant)</td>
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chart continued on page 5
Articles:

At a Glance: CDC Recommendations for Dental Water Quality

- Use output water that meets EPA regulatory standards for drinking water (500 CFU/mL of heterotrophic water bacteria) for routine dental procedures. Water used in health care should be at least as good as standard tap water.
- Use only sterile saline or sterile water when performing oral surgical procedures. Also, be sure to use devices specifically designed for delivering sterile irrigating fluids (e.g., bulb syringe, single-use disposable products, and sterilizable tubing). A traditional dental unit cannot deliver sterile water.
- Consult the dental unit manufacturer for advice on methods and equipment to maintain dental water quality. Only use the recommended products and protocols. Some dental equipment components may not be compatible with all waterline chemicals.
- Follow recommendations for monitoring water quality provided by the manufacturer of the unit or the waterline treatment product. Monitoring your dental unit water ensures that maintenance protocols are working and that water is of consistent quality.
- For devices that connect to the dental water system and enter the patient’s mouth, discharge water and air for at least 20-30 seconds between patients. This helps to flush out any patient material that may have entered handpiece turbines, air lines, or waterlines.
- Flushing waterlines at the beginning and end of the clinic day is not recommended for controlling dental water quality. It does not affect biofilm, and any reduction in output water bacterial counts are short-lived.
- Consult the dental unit manufacturer on the need for periodic maintenance of antiretraction mechanisms. Dental units that are more than 20 years old may have antiretraction valves that require maintenance.

Improving Dental Water Quality: A List of Currently Available Products

Sterile Water Delivery Systems
These FDA-cleared systems provide a single-use or autoclavable pathway for delivery of sterile water or solutions to handpieces and other devices. This list does not include dedicated oral surgery or implant handpieces.

- Satelec • (800)-289-6367 • www.acteongroup.com
  Suprasson P Max Ultrasonic Scaler (Allows sterile water delivery) K942139
- Lares Research • (800) 347-3289 • www.laresdental.com
  AquaSept (Formerly Northland SBP Unit) (Individual autoclavable reservoir units bypass dental lines to handpiece) K934436
- Odonto-Wave • (800) 368-5776 • www.odontoson.com
  Odontoson Ultrasonic Scaler (Provides sterile water delivery) K921893

Source Water Treatments
Water purifiers treat incoming water to remove or inactivate microorganisms. Unless the device also introduces a chemical agent to control biofilms, treatment water quality may not improve, but source water treatments can enhance the effectiveness of other treatment methods. These devices must be FDA-cleared.

- Crosstat/Waterclave • (913) 312-5860 • www.waterclave.com
  Waterclave/Crosstat (Source water treatment/delivery system) K001152
- DCI Int’l • (800) 624-2793 • www.dconline.com
  DCI Water Purifier (UV/filter for municipal water.) K971727
- DentalEZ/Star Dental • (800) DTE-INFO • www.dentalez.com
  AXCS Water Purifier (Sterltech water purifier) K000941
- Germiphene Corp • (800) 265-9931 • www.germiphene.com
  Odyssey I Dental Water Unit (Continuous ozone and silver germicide with UV water purifier) K964796
- Patterson Dental • (800) 328-5536 • www.vistaclear.com
  VistaClear Dental Waterline Treatment System (UV water treatment) per FDA Class I device, exempt
- Sterisil, Inc. • (877) 755-7873 • www.sterisil.com
  PureLine (Point-of-entry water treatment/holding device using nano-filtration, reverse osmosis, germicide, and UV light) K011681
  PureTube (Resin filter for junction box or water reservoir with continuous-release ionized-silver disinfectant) K011678

Need more info on dental unit waterlines? OSAP has the answers.

- Sign up for the OSAP 2004 Symposium in Miami, where Dr. Shannon Mills joins a panel presentation to address dental water quality.
- Check out From Policy to Practice: OSAP’s Guide to the Guidelines, which includes a detailed, how-to chapter on CDC’s 2003 recommendations for dental waterlines.
- See OSAP’s online Issue Focus: Dental Unit Waterlines at http://osap.org/issues/pages/water/index.htm
To help practices stay on track, OSAP provides this calendar listing typical schedules for periodic maintenance, record-keeping, and infection control activities. This schedule is intended only to serve as a guide. Proper practices, procedures, and maintenance schedules can vary according to the kinds of products used, the practice type, and patient volume. Always follow the device or equipment manufacturer’s instructions for maintenance and infection control.

For a monthly dental office calendar you can customize to best meet the needs and schedules in your practice, visit osap.org/calendars/index.htm. (Adobe Acrobat Reader required.)

Heads Up!

Don’t miss the OSAP 2004 Symposium: Paving the Road to the Future, June 10-13 at the Eden Roc Resort in Miami. Early registration discounts have been extended until April 30. The deadline for discounted room rates is May 1. Visit www.osap.org/training/symp/2004/index.htm for details.

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1. Although no measurable risk from exposure to dental unit water has been calculated, concern exists because:
   a. waterborne microorganisms have been linked to numerous infections in hospital settings and the community
   b. dental workers have been found to have altered nasal flora and higher titers of *Legionella*, suggesting exposure to the microorganism that causes Legionnaires’ Disease
   c. contaminated dental water may have been the source of infections in the gingival tissue of two immunocompromised patients
   d. all of the above

2. Biofilm can be found:
   a. only in dental unit waterlines
   b. in virtually all aquatic environments
   c. in carefully maintained sterile water systems
   d. all of the above

3. True or False: Microbial counts of greater than 1,000,000 CFU/mL have been reported in dental waterlines.
   a. True
   b. False

4. Within 5 days of installing new dental waterlines, microbial counts in treatment water can reach as high as __________ CFU/mL.
   a. 1,000
   b. 10,000
   c. 100,000
   d. 200,000

5. Self-contained water systems can reliably improve the quality of dental unit water:
   a. when used on their own, without other protocols
   b. when used with other water-quality control products and procedures
   c. without a filter
   d. all of the above

6. When sterile source water is used:
   a. sterile water can be delivered to the patient using a sterile disposable irrigating syringe
   b. sterile water can be delivered through the dental unit
   c. either of the above
   d. none of the above

7. True or False: Flushing waterlines at the beginning of the clinic day is an effective way to improve dental water quality.
   a. True
   b. False

8. Most microorganisms recovered from dental waterlines are:
   a. human flora
   b. highly infectious
   c. opportunistic waterborne organisms
   d. never harmful to humans

9. _____________ use autoclavable bottles and tubing to bypass the dental unit completely.
   a. All self-contained water systems
   b. Filters
   c. Sterile water delivery systems
   d. all of the above

10. Self-contained water systems:
    a. require no maintenance
    b. filter organisms out of source water
    c. can compromise water quality if not properly maintained
    d. use antiretraction valves
Did you know that everyday an estimated 1,000 eye injuries occur in American workplaces? Leslie Canham, RDA, of the California-based LESLIE Seminars urges all dental workers to take a moment to think about possible eye hazards in their practice settings and to be prepared to manage any injuries.

“Not wearing eye protection — or wearing the wrong type of eye protection — is the biggest cause of eye injury in any work setting,” she explains. Flying debris (as may be created during cavity preps) and chemical splashes are common contributors to eye injuries in dental settings. “About 40% of workers who have suffered an eye injury were wearing some form of eye protection, but the eyewear did not have side shields,” she notes.

“Always wear impact-resistant eye protection with solid side shields when you’re likely to encounter a hazard to your eyes. Look for eyewear that complies with ANSI Z87.1-1989, the American National Standard for Occupational and Educational Eye and Face Protection,” she recommends. Special eyewear also may help to protect eyes against potentially harmful light emissions from curing lights and lasers.

Even with personal protective equipment on hand, accidents can happen. “Every facility must have a properly functioning eyewash station to help manage any eye injuries,” states Ms. Canham. “Don’t wait until someone needs the eyewash station to make sure it’s up for the job.”

To ensure your eyewash station is ready and able at all times, routinely check your station for the following:

- Does the water turn on easily, with proper water pressure from both spigots?
- Is it positioned so you can put your eyes directly over the flow of water without having to turn your head sideways or without danger of bumping your head?
- Is it in an always accessible location (and not in a darkroom or bathroom that could be occupied or locked)?
- Is there a sign designating its location?
- Is it hooked up to cold water only?

Does everyone in your office know where it is located?

Are all staff trained to properly use the eyewash station?

Ms. Canham suggests reminding everyone on staff that in case of a chemical/body fluid splash to the eye, the affected area should be flushed for a full 15 minutes.

“Learn to protect yourself against eye injuries and exposures,” she says, “and always take proper precautions.

“Your eyesight is simply too valuable to lose.”

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An OSAP member since 2001, Leslie Canham, RDA, runs LESLIE Seminars. She lectures on OSHA compliance, infection control, dental law, and HIPAA. Contact Ms. Canham at 209-785-3903.

Do you have a practice tip you’d like to share with other OSAP members and subscribers? Send your suggestions for enhancing dental infection control and safety in practice to editor@osap.org. Be sure to include contact information, a photo, and a brief bio. Thanks!