Dental Unit Waterlines: OSAP Position Paper, March, 2000

This position paper updates the OSAP Dental Unit Waterline Statement originally published in January 1997. The paper was reviewed at the 1999 OSAP Annual Symposium, held June 24-27 in Cincinnati, Ohio.

Background

Microbial biofilms are ubiquitous in nature and can be found virtually anywhere there is moisture and a solid surface for attachment [1]. Consisting primarily of naturally occurring, slime-producing bacteria and fungi, biofilms in dental units form on the walls of the small-bore plastic tubing that delivers coolant water for the dental handpieces, sonic and ultrasonic scalers, and air-water syringes used in patient care [2, 3]. Levels of contamination in dental unit treatment water may exceed 1,000,000 colony-forming units per milliliter (CFU/mL). Although bacteria of possible human origin have been reported, most of the organisms recovered from dental unit waterlines occur naturally in aquatic environments.

Although there is no documented epidemiological evidence of a widespread public health problem, the presence in dental waterlines of potential human pathogens (including Pseudomonas aeruginosa [2], Legionella species [4, 5], and non-tuberculous Mycobacterium species [6]) suggests reason for concern. Both altered nasal flora [7] and serological evidence of exposure to Legionella bacteria [8, 9] have been reported in dental healthcare workers. A published case report associated two postoperative Pseudomonas infections in immunocompromised patients with exposure to contaminated dental coolant water [10]. The Occupational Safety and Health Administration (OSHA) has recently alerted its compliance officers of the potential for occupational exposure to bacteria from contaminated dental waterlines [11].

The 1993 Recommendations for Infection Control in Dentistry from the Centers for Disease Control and Prevention (CDC) state that sterile irrigating solutions should be used for all surgical procedures that involve the cutting of bone [12]. In 1995, the American Dental Association (ADA) convened an expert panel to review available information on dental unit waterlines. In December of that year, the Association published a statement on dental unit waterlines that challenged dental equipment manufacturers to produce systems that can reduce the level of bacteria in water used for non-surgical dental treatment to 200 CFU/mL or fewer by the year 2000 [13]. In November 1999, the ADA reaffirmed this goal and reported on scientific and technological developments that had occurred since the panel first convened [14].

Since 1995, there has been significant progress in developing reliable and economical engineering methods to control or prevent the formation of biofilm in dental unit waterlines. To date, the U.S. Food and Drug Administration (FDA) has given clearance-to-market a number of products. When used in a conscientiously applied manner, many of these agents and devices enable dentists to provide high-quality treatment water with minimal impact on dental equipment or materials. These products include chemical agents, independent water reservoirs, automated metering devices and microfiltration technology. Sterile water delivery systems, which employ either heat sterilizable or sterile disposable components, also are available. These systems completely bypass the dental unit. Methods for the clinical monitoring of water quality and compliance with treatment protocols also have been developed. (A current list of FDA-cleared products is available at www.osap.org or through the OSAP Central Office.)

OSAP generally concurs with the CDC and ADA recommendations on the use of coolant and irrigating solutions in dentistry and on the control of microbial contamination in dental unit waterlines. OSAP further urges dentists to take prudent measures to improve the quality of water used for dental treatment. The following statements
are intended to assist the dental profession and the dental manufacturing community with a framework for action to improve and maintain the quality of dental treatment water.

Exclusion

Please note that these statements are not intended to serve as a clinical manual for the control of waterline contamination. Dentists should contact the manufacturer of their dental equipment for specific guidance on methods to improve and maintain the quality of dental treatment water.

Statements on the Use of Coolant and Irrigating Solutions in Dentistry

Statement: The numbers of colony-forming units in water used as a coolant or irrigant for non-surgical dental treatment should be as low as reasonably achievable and, at a minimum, must meet nationally recognized standards for safe drinking water. Non-surgical procedures include most subgingival scaling or restorative procedures as well as initial access into the dental pulp.

Rationale: The 1995 ADA goal encouraged the development of methods to reliably produce dental treatment water that contains fewer than 200 CFU/mL of heterotrophic mesophilic water bacteria. The ADA goal was derived from engineering standards established in the field of hemodialysis, where colony counts higher than 200 CFU/mL have been linked to pyrogenic reactions in patients. This goal remains a viable engineering standard for manufacturers of devices or chemical agents intended to improve the quality of dental treatment water.

The Environmental Protection Agency (EPA), the American Public Health Association (APHA) and the American Water Works Association have set a maximum limit for heterotrophic mesophilic water bacteria in drinking water at 500 CFU/mL [15, 16]. While it is clear that dental water should contain colony counts that are as low as reasonably achievable, there is little scientific evidence that water that meets drinking water standards poses a health hazard for immune-competent individuals. Although procedures within the gingival sulcus may technically expose the vascular system, sulcular tissues are already colonized with microorganisms. The decision to use clean or sterile water during such procedures should be based on the invasiveness of the procedure, the patient's immunologic status, and other potential risk factors for infections, such as infective endocarditis.

Since initial access into the pulp chamber may be performed in conjunction with restorative dental procedures, the use of dental unit water that meets drinking water standards is acceptable for endodontic access procedures, but sterile solutions are preferred for subsequent canal preparation and are required for endodontic surgery.

Statement: Sterile solutions that meet the appropriate standards described in the United States Pharmacopoeia (USP) should be used for all dental procedures that involve the intentional penetration, incision, excision, abrasion, or ablation of intact, non-sulcular oral mucosa to expose normally uncontaminated soft tissue or bone.

Rationale: OSAP concurs with the 1993 recommendation of the CDC that only sterile solutions should be used for surgical procedures that involve the cutting of bone [12]. The OSAP statement further clarifies this position by including all other surgical procedures that expose normally uncontaminated tissues and result in penetration of the vascular system. The USP sets standards for sterile solutions that assure that they are free of viable microorganisms and have acceptably low levels of bacterial endotoxin and other potentially harmful substances [17].

Statements on Methods to Improve and Maintain the Quality of Water Used in Dental Treatment

Statement: OSAP cautions that flushing waterlines for several minutes prior to beginning dental treatment without additional treatment to remove or suppress microbiologic contamination should be used only as an interim measure until more effective methods can be applied. The practice of briefly flushing waterlines between
patients to remove patient material potentially retracted during treatment as recommended by the CDC should be continued.

Rationale: The efficacy of mechanical flushing alone to control microbial contamination in dental unit water is not well supported by the scientific literature. Although flushing can temporarily reduce the number of organisms suspended in dental waterlines, there is no predictable effect on adherent biofilms. Bacterial aggregates breaking free from the biofilm have been shown to re-contaminate dental unit water during the course of subsequent clinical treatment [18, 19]. Flushing for several seconds between patients, however, may remove materials that may have entered the water system during patient treatment [12].

Statement: Devices that provide surgical irrigation in the oral cavity must use sterile, non-pyrogenic reservoirs or tubing for solutions that enter the surgical site. All components of this pathway must be single-use disposable or compatible with heat sterilization methods used in outpatient dental settings. Manufacturers should test all reusable devices to validate the efficacy of recommended sterilization procedures.

Rationale: Examples of devices covered by this statement include oral surgery and implant handpieces, sonic and ultrasonic scalers used during periodontal surgery, and surgical irrigation devices such as bulb syringes. Use of sterile, non-pyrogenic tubing and reservoirs for surgical coolant or irrigants assures that these solutions meet standards of care for surgical procedures. Acceptable sterilization methods should include steam autoclaves or alcohol/formaldehyde chemical vapor sterilizers.

---

**Statements on the Responsibilities of Manufacturers of Devices and Chemical Agents for Improving the Quality of Dental Treatment Water**

Statement: OSAP discourages the use of low-temperature water-heating systems in dental units because of their potential to increase the numbers and/or pathogenicity of waterline microorganisms.

Rationale: Low-temperature dental-unit-water heaters are designed to maintain dental treatment water at or near human body temperature. This may stimulate bacterial proliferation and could select organisms pre-adapted to growth at body temperature. Water in separate reservoir systems that are maintained at room temperature can provide adequate patient comfort while discouraging the growth of potential human pathogens. Chemical agents used for waterline treatment also may damage water heaters.

Statement: Manufacturers of devices and solutions marketed for the control of microbial contamination in dental unit water systems are responsible for validating the safety and efficacy of products and obtaining appropriate regulatory clearance or registration.

Rationale: Untested devices and protocols may be ineffective or potentially harmful to patients, dental healthcare workers, and dental equipment. Dental equipment manufacturers are legally and ethically obligated to ensure the safety and efficacy of devices that claim to improve the quality of water used in dental treatment.

Statement: Commercial devices and chemical agents marketed for the control of microbial contamination in dental unit water systems should be cleared for market by the FDA and/or registered with the EPA as appropriate. A fully workable process to accomplish this does not presently appear to exist. Therefore, both FDA and EPA should work with professional organizations, the dental industry, and standards-setting bodies such as the American National Standards Institute (ANSI) to develop a workable strategy for clearance or registration of products intended to improve and maintain the quality of dental treatment water.

Rationale: The FDA classifies dental water treatment and delivery systems as medical devices subject to pre-market clearance requirements under the Federal Food, Drug, and Cosmetic Act (FD&C). The FDA also must clear-for-market chemical agents that are continuously present in dental treatment water. As a result of congressionally mandated agreements between the two agencies, all other chemical germicides with dental waterline claims now must be registered with the EPA as directed by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). OSAP is aware that neither EPA nor FDA presently have adequate regulatory processes for this commercial application. This regulatory impasse has created much confusion among dentists...
and the dental industry and serves to discourage the development, marketing and use of safe and effective products.

Statement: The manufacturers of chemical agents must supply Material Safety Data Sheets and other pertinent information as required by OSHA.

Rationale: Chemical agents used for the control of microbial contamination of dental treatment water must be safe for patients and healthcare workers when used as directed. Furthermore, if the chemical agent is not completely removed, it must leave only safe levels of residues in dental treatment water. All chemicals used in dental unit water systems must comply with all applicable federal and state occupational health and safety requirements.

Statement: Chemical agents that are continuously present in dental water supplies or that leave detectable residues should be compatible with dental restorative materials. In order to claim that an agent has no effect on dental materials, manufacturers should perform appropriate testing and inform users if the water-treatment solutions may be incompatible with specific dental restorative materials.

Rationale: Chemical agents and residues present in dental treatment water may have unintended effects on dental restorative materials. Studies have been published suggesting that some products may contain substances that can interfere with dental adhesive materials 20, 21.

Statement: Devices and chemical agents commercially marketed for the control of microbial contamination in dental unit water systems should be compatible with the materials used in the construction of the dental units. Manufacturers should perform appropriate compatibility testing with commonly used dental unit waterline materials and must inform users if devices or solutions may be incompatible with dental delivery systems.

Rationale: Chemical agents may have unintended effects on materials used in the construction of dental water delivery systems and may damage components or produce potentially hazardous disinfectant byproducts [22]. This concern is most acute for devices or chemical agents that may be used on a wide variety of dental units.

Statement: Dental unit water systems must be designed prevent retraction of patient material to the maximum extent possible. Manufacturers should provide instructions for periodic testing, maintenance, or replacement of components intended for this purpose.

Rationale: Retraction of patient material by dental water systems offers the potential for patient-to-patient transmission, either directly or by permitting colonization of waterline biofilms by organisms from the oral cavity. There is evidence that the performance of anti-retraction devices—whether active or passive—may degrade over time [23]. Manufacturers should be aware of the limitations of the devices installed on their dental units and provide users with appropriate guidance to maintain optimal performance.

Statement: All devices and solutions marketed for the purpose of improving, maintaining, or monitoring the quality of dental treatment water must have clearly written precautions and instructions for installation, use, and maintenance. Ideally, devices and protocols should be designed to minimize user intervention.

Rationale: Treatment methods for the control of microbial contamination of dental treatment water may be technique-sensitive. Simple, well-written instructions can greatly enhance the probability of clinical success and reduce the potential for damage to equipment or injury to staff or patients. Greater automation of procedures can save time and decrease the potential for human error.

Statement: Manufacturers of devices and chemical agents for improvement of dental water quality should use validation studies to develop outcome measures and management tools for clinical monitoring. Clinical monitoring is a quality-assurance process and is not intended to re-validate process efficacy. Microbiologic methods should be consistent with recognized standards for measurement of heterotrophic water bacteria [16, 24].

Rationale: Since manufacturer-recommended treatment methods should be validated by laboratory and clinical studies prior to marketing, the primary purpose of monitoring should be to identify technique errors or non-
compliance. Because non-compliance has been identified as an important cause of clinical failure, monitoring also can provide a positive-reinforcement feedback loop for the dental staff [25]. Use of the heterotrophic plate count (HPC) or other scientifically validated methods can be correlated with the assessment methods used by public health authorities to test drinking water.

Statement: Routine testing for specific organisms such as Legionella or Pseudomonas is not recommended. Such testing should only be performed to investigate a suspected waterborne illness as directed by local health authorities.

Rationale: Just as there is little need to culture environmental surfaces or instruments following disinfection and sterilization procedures, there are few reasons to routinely test for potential pathogens such as Legionella or Pseudomonas in dental unit water, since most treatment methods target the entire biofilm, rather than specific organisms. Current CDC guidelines do not recommend routine environmental testing in healthcare settings [26]. A negative test for a difficult-to-culture pathogen such as Legionella at a given point in time may give false reassurance of the safety of dental treatment water. Unless a different treatment regimen will be used when specific organisms are recovered, there is no need for such testing. The documented isolation of pathogenic organisms from dental water systems also may have medico-legal implications for the dental practice.

---

**Statement on the Responsibilities of Clinicians**

Statement: Dental practices should immediately take prudent measures to provide quality water for dental treatment and ensure a safe and healthy environment for patients and staff. OSAP recommends that all practicing dentists take the following steps:

1. Review the scientific literature to gain an understanding of the nature and potential risks associated with dental waterline contamination.

2. Contact the manufacturer of dental units and other devices that use water to obtain current recommendations on how to maintain the quality of dental treatment water.

3. When replacing dental units and devices, select products that can economically and reliably maintain water quality.

4. When purchasing new units, retrofit devices, or solutions, obtain relevant information from the manufacturer on the safety, efficacy, and cost effectiveness of each product.

Rationale: The use of water for dental therapeutic procedures that fails to meet established standards for drinking water is inconsistent with recognized standards of infection control and can potentially undermine public confidence in the dental profession. The present lack of epidemiologic evidence of illness or injury among patients or dental healthcare workers does not provide a valid rationale for inaction.

---

**Conclusions**

Scientifically validated treatment methods are currently available to permit delivery of dental treatment water of acceptable microbiologic quality with minimal risk to patients, staff, and dental equipment. To best ensure the health and safety of dental patients and staff, manufacturers of dental equipment, devices, and chemical agents intended to improve and maintain the quality of dental treatment water should base their efforts on a strong foundation of peer-reviewed science. Federal regulatory agencies must develop workable clearance and registration processes to help ensure the safety and efficacy of products intended to maintain or improve the quality of dental treatment water. OSAP believes that these goals can best be accomplished by collaboration among government agencies, industry, academia, and clinicians. OSAP and other professional organizations must encourage an aggressive research agenda on this issue and continue their efforts to educate the dental profession.
Glossary

Adhesion/attachment* A stable interaction of a cell with respect to a surface. Living cells actively excrete holdfast chemicals from their surface to anchor themselves to a substratum.

Antimicrobial agent* An agent that kills or inhibits microbial growth. May include materials also described as biocides, disinfectants, or germicides. Use and definitions of these terms may be further specified in certain federal regulations or statutes (although neither FDA nor EPA currently recognizes these terms as legal for claims regarding dental unit water systems).

Biofilm Slime-producing bacterial communities that also may harbor fungi, algae, and protozoa. These microorganisms colonize and replicate on the interior surfaces of waterline tubing, creating adherent microbial accumulations.

Biocide* An agent capable of killing microorganisms; however, it may not be 100% effective. In biofilm usage: A chemical used to disinfect or remove biofilm in order to control a detrimental effect of the biofilm. See also antimicrobial agent, disinfectant, germicide.

Colony-forming unit* abbr.: CFU. The minimum number of separable cells on the surface of or in semi-solid agar medium which gives rise to a visible colony of progeny on the order of tens of millions of cells in number. CFUs may consist of pairs, chains, and clusters as well as single cells and are often expressed as colony-forming units per milliliter (CFU/mL).

Dental treatment water Non-sterile water used for dental therapeutic purposes, including irrigation of nonsurgical operative sites and as a coolant for highspeed and ultrasonic instruments.

Dental unit waterlines (DUWL) Small bore tubing, usually made of plastic, used to deliver dental treatment water through a dental unit.

Disinfectant as defined in current FDA documents: A chemical agent that eliminates a defined scope of pathogenic organisms, but not necessarily all microbial forms (e.g., bacterial endospores). (Rutala, 1990)

Disinfection as defined in current FDA documents: The destruction of pathogenic and other kinds of microorganisms by thermal or chemical means. Disinfection is a less lethal process than sterilization, since it destroys most recognized pathogenic microorganisms, but not necessarily all microbial forms, such as bacterial spores. Disinfection processes do not ensure the margin of safety associated with sterilization processes. (AAMI/Association for the Advancement of Medical Instrumentation, 1995)

Drinking water as defined by EPA microbiologic standards: The Surface Water Treatment Rule includes the following limits on microbial contaminants in surface water or ground water under the direct influence of surface water:

- Giardia lamblia: 99.9% killed/inactivated
- Viruses: 99.99% killed/inactivated
- Legionella: No limit, but EPA believes that if Giardia and viruses are inactivated, Legionella also will be controlled.
- HPC: No more than 500 bacterial colonies per milliliter.
- No more than 5.0% samples total-coliform-positive in a month. All total-coliform-positive samples must be analyzed for fecal coliforms. There cannot be any fecal coliforms. (Fecal coliforms and Escherichia coli indicate that water may be contaminated with human or animal wastes that can cause diarrhea, cramps, nausea, headaches, or other symptoms.)

Germicide as defined in current FDA documents: An agent that destroys microorganisms, especially pathogenic organisms. Other categories of agents that use the suffix "-cide" (e.g., virucide, fungicide, bactericide, sporicide,
tuberculocide) destroy the microorganism identified by the prefix. (Block, 1991) See also antimicrobial agent, biocide, disinfectant.

Glycocalyx* Extracellular polymeric material produced by some bacteria. The term was initially applied to the polysaccharide matrix excreted by epithelial cells forming a coating on the surface of epithelial tissue. A general term for polysaccharide compounds outside the bacterial cell wall, it also is called slime layer, extracellular polysaccharide (EPS), or matrix polymer.

Heterotrophic bacteria* Those bacteria that require an organic carbon source for growth, i.e., they derive energy and carbon from organic compounds. The modifier "mesophilic" is used to describe bacteria that grow best within the middle ranges of environmental temperature.

Heterotrophic plate count bacteria* abbr.: HPC bacteria. Those bacteria that can be grown on non-selective heterotrophic medium plates.

Independent water reservoir A container used to hold and supply water or other solutions to handpieces and air water syringes attached to a dental unit. The independent reservoir also isolates the unit from the public water system. May be provided as original equipment or as a retrofit device on all modern dental units.

Medical Device as defined by the Food, Drug, and Cosmetic Act: An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory that is (1) recognized in the official National Formulary, the United States Pharmacopoeia, or any supplement to the aforementioned; (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in man or animals; or (3) intended to affect the structure or any function of the body of man or other animals, does not achieve its primary intended purposes through chemical action within or on the body of man or other animals, and is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

Microfiltration Use of membrane filters to trap microorganisms suspended in water. In dental usage, filters are usually installed on dental unit waterlines near the point of use as a retrofit device. Microfiltration commonly occurs at 0.03 to 10 microns (micrometers). Sediment filters commonly found in dental unit water filter regulators range from 20 to 90 microns and do not function as microbiological filters.

Retraction The entry of oral fluids and microorganisms into waterlines as a result of negative water pressure or other hydrodynamic processes. Also referred to as "suck-back."

Sterile as defined in current FDA documents: The state of being free from all living microorganisms; in practice, usually described as a probability function, e.g., as the probability of a surviving microorganism being one in a million. (AAMI, 1995)

Sterile water for irrigation Water described in an official monograph in the current U.S. Pharmacopoeia with various specifications, including limits on pyrogens (bacterial endotoxin) and other impurities. "Sterile water for irrigation" is a "finished" product that is packaged and labeled for non-intravenous use in surgical irrigation.

* Denotes definitions used with permission of the Center for Biofilm Engineering, Montana State University.

Statement Editors**: Shannon E. Mills, DDS, US Air Force
Phil Westover, A-dec, Inc.

Working Group Members**: Juliet Alsina, Millipore Corporation
Nancy Andrews, RDH, PERIOgiene Inc.
Bill Bird, DDS, DPH, University of California, San Francisco, School of Dentistry
Dave Blazo, Pall Corporation
Affiliations are listed for identification only. The opinions expressed in this position paper are those of the Organization for Safety & Asepsis Procedures and do not necessarily express the official position of any other organization, corporation, government agency, or academic institution.

References cited


Internet Resources


Organizational information

OSAP is a group of dentists, auxiliary staff, allied health professionals, government representatives, industry members, academicians, and researchers devoted to advancing the art and science of dental infection control and practice safety. A clearinghouse of information on dental asepsis and safety issues, OSAP works to educate the dental community through its publications, annual symposia, and web site (www.osap.org). For additional information on the organization and the efforts of its educational foundation, contact OSAP at 800-298-6727.