SPECIAL REPORT

DENTAL WATERLINES:

Understanding and Controlling Biofilms and Other Contaminants

by
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Possibly The Most Concerning Dental Issue In The Last 30 Years

How to WIN the Fight Against Bacteria, Biofilms & Other Contaminants While Also Protecting Your Patients, Your Staff and Your Practice

Here are just a few of the questions and topics that will be addressed in this Special Report

This report is designed to provide background information about the topic of dental waterline contamination. Dental professionals around the world have been made aware of the problem but really don't know exactly what to do about it. An attempt has been made in this report to cover basic concepts, issues of concern and possible corrective measures.

Data was gathered from numerous sources including textbooks, magazine and trade journal articles, government publications and websites as well as personal interviews and experience. Sources for information used or cited have been credited in the references section. Any source not properly credited is purely inadvertent.

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Are dental waterlines really contaminated?

In a word – yes. It's estimated that the vast majority of all dental waterlines in the United States and around the world are contaminated with biofilms. Without question, the colonization and proliferation of microorganisms in the dental waterlines is well documented.

So what does "contaminated" mean? Relative to biofilms, bacteria and other microorganisms, the American Dental Association (ADA) has established a target of less than 200 colony forming units per milliliter (cfu/ml) of heterotrophic, mesophilic organisms in dental waterline effluent. They established this goal in 1995 and set a target date for accomplishment by 2000. The goal has not been met.

The Centers for Disease Control and Prevention (CDC) indicates that documented contamination levels for dental waterlines can run between 10,000 and 10,000,000 cfu/ml. To give you an idea of severity, the level of "coliform" bacteria allowed under the Safe Drinking Water Act's primary maximum contamination level (MCL) is zero (0). The maximum goal for heterotrophic plate count (HPC) organisms in drinking water is to be less than 500 cfu/ml. And, the maximum HPC level in dialysis systems is 200 cfu/ml – the same "goal" level set by the ADA.

Bacterial contamination exists to varying degrees in virtually all water pipes – why is it so much worse in dental waterlines?

According to Raghunath Puttaiah, BDS, MPH and Robert A. Cederberg, MA, DDS from chapter six of Infection Control and Safety Handbook, biofilm contamination is a dynamic process caused by many factors that include:

1. Long periods of stagnation
2. High surface to volume ratio
3. Nutrient content of water for the microbial survival
4. Mineral content and hardness of water facilitating coating of the lumen
5. Fluid dynamics
6. Low flow rate
7. Microbial quality of the source water entering the system

In a home setting, the amount of water used is estimated to be from 50-75 gallons per person per day for all uses. This would include drinking, bathing, flushing toilets, washing dishes, clothes, etc. A typical home water system with a family of four would have a daily consumption of 200-300 gallons. Further, the flow rate would range between one to ten gallons per minute. And, businesses can use hundreds or thousands of gallons per minute. The point here is that normal water systems have a reasonably high "flow rate" and large daily consumption when compared to the dental office.

A typical dental office may only use from 250 ml to two (2) Liters of water per operatory per day (averaging 750 ml to 1 Liter). This is an extremely small volume of water. And the speed it passes through the dental tubing may only be 30-50 ml per minute and for only short periods. In essence, the water "sits" in the tubing in an almost stagnant manner all day. Worse yet are the long periods of quiescence throughout the nights and weekends.

Another problem with dental waterlines is the way water flows through the tubing. Dental waterlines exhibit what is called "laminar" flow. This is a phenomenon where the water closest to the inner wall of the tubing has virtually no movement and water simply moves through the very center of the tubing. This means the area where biofilms attach themselves is unaffected by any aggressive flow that may occur. A desirable flow characteristic would be a "radial" configuration where the full diameter of the tubing experiences a flow velocity with maximum speeds found at the tubing wall. However, radial flow cannot be accomplished in dental tubing therefore biofilms are able to grow quickly in the "quiet zone" found on the surface of the lumen wall. We'll talk in much greater detail about bacteria and exactly how biofilms are thought to form later in this report.

Is dental delivery equipment actually causing the problem?

Modern dental delivery equipment has made the practice of dentistry much easier and convenient. The use of air, water, foot switches, etc. to operate necessary tools is invaluable. However, the design includes tiny tubes, junction blocks with numerous small ports and small diameter tubes that "terminate" with high or low speed handpieces, air/water syringes, scalers, etc. By design each tube creates a "dead leg" which is a huge contributor to biofilm development. For example, whether an organism enters the system through the municipal water connection, a bottle system or is sucked back from the patient's mouth, it will attempt to establish residency in the tubing or other component of the system. If one or more of the tools are not used frequently, conditions are made even better for the development of damaging biofilms due to "quiet" conditions in that particular tube or tubes. Organisms leaving the rapidly growing biofilm in essence "back feed" from the colonized tubing and seek new areas to create additional biofilms.

Dental equipment manufacturers have been criticized by industry scientists for not correcting current designs that actually promote waterline contamination and biofilm development. The following are several such comments:

"The design of dental unit water systems is the cause of high organism counts, whether in municipal or independent reservoir hookups. Therefore, responsibility for the problem rests mainly on dental equipment manufacturers." – *Dentistry Today*, January 1998

"Clearly dental unit water quality questions should have been eliminated years ago by altering dental unit designs. Lack of action by dental unit manufacturers before the Dec. '95 ADA declaration is questionable, but failure to act in the 4 years since the declaration has resulted in widespread embarrassment to dental clinicians. Since clinicians can only treat the effects & have no way to eliminate the problem, responsibility for a reliable, practical, & permanent fix rests solely with those who design, build, & sell dental units." – CRA Newsletter, October 1999

"We call on the dental unit manufacturers to fix the dental unit suckback & waterline problems. These problems are caused by designs the dental unit manufacturers have chosen to use since the early 1960's. It is not only time, it is well past time to fix these problems. Lack of action since the ADA's goal statement in Dec. 1995 is appalling & shows negligence in reacting to an urgent need." – CRA Newsletter, March 2000

As we've already discussed, there are bacteria in most water supplies but are found in low quantities and generally harmless to healthy individuals. In trying to make dentistry even more convenient for practitioners, the designs used by manufacturers have inadvertently created a situation that truly encourages all kinds of microbiological growth.

Are my staff and patients at any real risk due to the waterline problem?

According to the Centers for Disease Control and Prevention (CDC), reports in the scientific literature suggest that the microbiological quality of water used in dental treatment equipment frequently may not be acceptable for dental care delivery. This issue was first reported more than 30 years ago and recently has resurfaced due to an increased awareness of potential occupational hazards and concern about the increasing numbers of immunocompromised patients seeking dental treatment. As mentioned earlier, levels of microbial contamination as high as 10,000 to 10,000,000 cfu/ml have been documented. As a point of reference the Federal Safe Drinking water Act for potable water is around 500 cfu/ml of non-coliform bacteria.

The CDC further states that, in general, most organisms found in dental unit waterlines (DUWLs) are non-pathogenic for immunocompetent patients. To date, CDC is unaware of any serious health effects documented among patients or workers that can be directly related to contact with dental unit water. A few studies have suggested that dental workers have higher titers of *Legionella* antibodies in comparison to control populations. Also, in Great Britain the dental water may have been the source for localized *Pseudomonas* infections of two immunocompromised patients. "Yet, despite the absence of documented health effects, contact of the patient's open wound, mucous membrane or body cavity with water of poor microbiological quality is inconsistent with infection control principles." This is particularly true when methods to assure better water quality are available or can be rapidly developed.

As reported by the CDC, the 2000 Emerging Infectious Diseases Conferences held in Atlanta, Georgia focused on waterborne disease outbreaks and world water issues. The purpose of this conference panel was to discuss recent trends and research studies that link drinking water to infectious diseases. Recent events have raised new questions about drinking water and health, including highly publicized outbreaks of illness from and concern about endemic disease from drinking water.

Paul R. Hunter, consultant medical microbiologist and Director of the Chester Public Health Laboratory and honorary professor of epidemiology and public health at the University of Central Lancashire, presented World Health Organization data that showed high morbidity and death rates worldwide due to consumption of unsafe drinking water. Dr. Hunter noted the wide variety of microbes recognized since 1980 as waterborne disease agents, including *Cryptosporidium*, *Cyclospora*, *E. coli* O157, *Legionella*, *Helicobacter pylori*, hepatitis E virus, *Toxoplasma*, and others.

Mark W. LeChevallier, director of research at the American Water Works Service Company, discussed health concerns regarding biofilms. He indicated that biofilms can harbor, protect, and allow the proliferation of several bacterial pathogens, including *Legionella* and *Mycobacterium avium* complex (MAC). Dr. LeChevallier stated that a number of waterborne disease outbreaks have been linked to distribution system deficiencies. Among the agents of nosocomial waterborne disease is

MAC. This opportunistic bacterial pathogen lives in water, is resistant to water disinfection (much more so than *Giardia* cysts), and grows in pipe biofilms. More on this organism later.

CDC's National Center for Infectious Disease outlines aggressive plans in their strategic plan entitled *"Emerging Infectious Diseases:A Strategy for the 21st Century."* The CDC will continue to support and encourage research to create tools for the prevention and control of infectious diseases, including the development of drugs and vaccines, methods for disinfecting food and water, and to promote strategies for the prevention and control of infectious diseases. CDC will also continue to study the role of the hospital environment in facilitating the spread of infections and to identify new ways of preventing these infections. CDC's efforts include:

• Learning how bacteria interact with environmental surfaces and medical devices, using scanning electron microscopy and other tools.

• Determining how to control biofilms on medical devices and tubing, in water systems in medical settings such as water lines in dental equipment, which can harbor infectious organisms.)

• Determining whether microbes are developing resistance to environmental disinfectants.

• Assessing new approaches to filtering air and otherwise reducing the spread of airborne organisms.

Of course, much of the airborne problem seen in dental operatories is due, in part, to the aerosols created when high speed handpieces contact microbiolocially impure water.

At the101st General Meeting of the American Society for Microbiology held May 20-24, 2001, in Orlando, Florida, Session 305/Q, Paper Q-435 presented results of a study that quantified aerosolized bacteria in dental treatment operatories. The report, in part, reads as follows:

"Fluorescence microscopy methods allow a good and rapid evaluation of the bioaerosol levels. We think that culture methods may lead to the underestimation of the microbial burden in this type of environment and that some treatments may be responsible for the release of bacteria present in dental unit waterlines. It has been shown that these small tubings hold high concentration of waterborne microorganisms.

"This preliminary study shows that dental treatments may release high bioaerosol concentration and that, as previously demonstrated, dental unit waterlines could act as a reservoir for bacteria to become airborne through aerosolization. The use of non-culture related methods is essential in order to evaluate adequately the airborne bacterial burden. It is now well accepted that bioaerosols are produced when high-speed instruments are used in dental treatments. Workers could be chronically exposed to those bioaerosols that contain bacteria that are mouthborne (patient's mouth microflora) or waterborne (biofilm contaminating the dental unit waterline). The aim of this study was to compare the effectiveness of fluorescence microscopy and culture methods in the evaluation of bacterial bioaerosols produced during two types of treatment: operative dentistry and cleaning with ultrasonic scalers.

"Fluorescence microscopy showed very high levels of bacteria both in air and water samples, reaching up to 8.4 X 10^5 bacteria/m^3 and 2.1 X10^6 bacteria/ml, respectively. Culture on various media allowed an average recovery of 0.45% for air sampled during ultrasonic scaling. In conclusion, dental offices workers are exposed to high bioaerosol concentrations and usual culture method underestimate this exposure and do not take waterborne bacteria into account."

In an article entitled "Waterborne Biofilms and Dentistry: The Changing Face of Infection Control" that appeared in the *Journal of the Canadian Dental Association* in November 2000 (Vol. 66 No. 10), Jean Barbeau, PhD, also shares concern for potential health risks for the dental staff and patients. Dr. Barbeau comments on a 1987 report published in the *British Dental Journal* as follows:

"The paper presented 2 case reports in which medically compromised patients had been infected with *P. aeruginosa* originating form dental unit water supplies. In 1994, a dentist's death form pneumonic legionellosis was attributed to the inhalation of the pathogen during use of handpieces. Although it could not be proven definitively that the dental unit water was the culprit, suspicion ran high. Isolated cases of amoebic eye infection, brain abscess and gastrointestinal disorders have been reported, but strong evidence is lacking. Nonetheless, a lack of evidence does not constitute absence of evidence."

Dr. Barbeau identifies ways a patient undergoing dental care may be infected with microorganisms:

- Hematogenous dissemination during surgical procedures (theoretical but possible)
- Local mucosal (oral or conjunctival) contact
- Ingestion
- Inhalation

The article continues – "The evidence suggests that dental personnel are continually exposed to waterborne microorganisms. For example, the prevalence of antibodies to *L. pneumophilia* was significantly higher among dental personnel than in a control population (34% and 5% respectively), and the nasal flora of dentists may have a higher proportion of waterborne *Pseudomonas* spp."

More risks for dental staff and patients

In an article entitled "Causes and prevention of microbial contamination of dental unit water," Dr. Caroline Pankhurst (UK), Dr. R.G. Woods (Australia) and Professor N.W. Johnson (UK), indicate the following:

"Currently, there is no clinical evidence of a widespread public health problem from exposure to DUW. Nevertheless, <u>the goal of infection control is to minimize the potential risk from exposure to known pathogens and create a safe working environment in which to treat patients</u>. The ever increasing number of patients who are either immunocompromised or immunosuppressed due to steroids, drug therapy, alcohol abuse or systemic disease has produced a substantial number of patients susceptible to environmental, waterborne opportunistic pathogens such as those found in DUW."

A major concern is that of some of the primary respiratory pathogens like *Legionella pneumophilia* and non-pneumophilia spp. as well as *Mycobacterium* spp. found in waterlines can cause pneumonia, flu-like symptoms and wound infections. Pankhurst et al. indicate that, "High numbers of non-tuberculous mycobacterium may be swallowed, inhaled or inoculated into oral wounds during dental treatment with the potential for colonisation, infection or immunization."

Acanth-amoeba has also been recovered from dental waterline biofilms and may be responsible for amoebic keratitis in contact lens wearers. Pankhurst et al. report that it's unknown if this pathogen presents significant risk during dental treatment but routine use of eye protection should shield the eyes sufficiently from exposure.

The authors point out that, in addition to patients, members of the dental team also inhale aerosols generated by dental equipment every day. As others have reported, dental staff tend to have abnormal nasal flora linked to the water system and suffer more respiratory infections compared to both their medical colleagues or the general public.

"Dentists have higher rates of antibodies to *Legionella* compared with the general public," the article states. "The magnitude of *Legionella* antibody titres correlated directly with the number of years spent working in a dental surgery, suggesting that aerosols generated from DUW are the likely source of exposure. *Legionella* spp have been detected in 60% of DUW samples and *L. pneumophilia* the causative agent of Legionnaire's disease in 8%. High concentrations of *Legionella* are usually required to initiate infection in healthy people. Significantly from a public health standpoint quantitative measurements showed that 19% of the DUW samples had high counts of greater than or equal to 10,000 *Legionella*/ml, whereas none of the cold water municipal samples tested had counts in this category. A single fatal case of *Legionella dumoffi* pneumonia has been reported in a dentist exposed to contaminated water from his practice."

The Occupational Safety & Health Administration (OSHA) has also registered a concern for Legionnaires disease stating that "More than 34 species of *Legionella* have been identified, and more than 20 linked with human diseases. … *L. pneumophila* has also been implicated in wound infections, pericarditis, and endocarditis without the presence of pneumonia." The likelihood of contracting Legionnaires' disease is related to the level of contamination in the water source, the susceptibility of the person exposed, and the intensity of exposure to the contaminated water. Disease transmission usually occurs via inhalation of an aerosol of water contaminated with the organism. Aspiration of contaminated water into the lungs may also cause the disease.

Low and even nondetectable levels of the organism can colonize a water source and grow to high concentrations under the right conditions. Conditions that promote growth of the organism include heat, sediment, scale, and supporting (commensal) microflora in water. Common water organisms including algae, amoebae, and other bacteria appear to amplify *Legionella* growth by providing nutrients or harboring the organism. Because of its ability to remain viable in domestic water systems, it is capable of rapid multiplication under the proper conditions.

According to OSHA, water conditions that tend to promote the growth of *Legionella* include water stagnation, temperatures between 20° and 50°C (68° - 122°F) the optimal growth range being 35° - 46°C [95° - 115°F]), a pH between 5.0 and 8.5, sediment that tends to promote growth of commensal microflora and microorganisms including algae, flavobacteria and *Pseudomonas,* which supply essential nutrients for growth of *Legionella* or harbor the organism. OSHA indicates a common sources of water contaminated by *Legionella* include dental water lines, which are frequently maintained at temperature above 20°C (68°F) and sometimes as warm as 37°C (98.6°F) for patient comfort.

Raghunath Puttaiah, BDS, MPH and Robert Cederberg, MA, DDS, in their handbook on infection control, indicate that the colonization and proliferation of many and varied species of microorganisms in dental unit waterlines has been well documented. They indicate three genera are of particular concern for the dental office – *Pseudomonas, Mycobacteria* and *Legionella*.

***Pseudomonas** cepacia* (Gram negative bacillus) has been spread to patients in hospital settings through its presence in aqueous disinfectants. "This species is very resistant to chemical agents and the colonization of this species of bacteria has been demonstrated when reservoirs of chlorhexidine gluconate have been "topped-up" without cleaning the reservoirs first," indicated the authors. Water spray aerosols are commonplace in the dental setting (high speed handpiece operation and air water syringe rinsing with high speed evacuation). Aerosols generated by the water-cooling component of dental handpieces were found to be the source of subclinical infection with ***Legionella** pneumophila* in a dental school environment.

"Fotos et al. investigated exposure of students and employees at a dental clinic and found that of the 270 sera tested, 20% had significantly higher IgG antibody activity to the pooled *Legionella* spp. antigen as compared with known negative controls. Reinthaler et al. found a high prevalence of antibodies to *Legionella pneumophila* among dental personnel. Their study demonstrated the highest prevalence (50%) among dentists who were constantly exposed directly to the aerosols generated when high-speed drills and sprays were used. Atlas et al. found that 68% of DUW samples collected from 28 dental facilities in six U.S. states showed presence the of *Legionella* spp. This study also showed that 61% of water samples of comparative potable water from domestic, institutional faucets and drinking water fountains also contained *Legionella* spp. and that there was no significant difference between the two."

With over 90 recognized species, 20 of which are known to cause disease in humans, ***Mycobacteria*** are becoming of more concern in the dental office. According to recent information provided by the EPA, non-tuberculosis *Mycobacteria* (NTM) are ubiquitous in the environment and have been isolated from numerous water sources including waste water, surface water, swimming pools and, most importantly, tap water.

Mycobacteria are rod-shaped bacteria that require oxygen for growth. Piped water supplies are readily colonized by this organism. Their thick, waxy outer coating enables them to thrive in aquatic situations and biofilms serve as reservoirs for these opportunistic pathogens. Unfortunately, NTM can be relatively resistant to standard water disinfection procedures.

Waterborne NTM have been associated with nosocomial outbreaks worldwide with exposure pathways of potential concern being ingestion, inhalation and entry of orgaisms through broken skin or tissue. Clinical syndromes include pulmonary infection, infections of the lymph nodes, bacteremia, ear infection, skin, soft tissue and catheter-associated infection. Although the general population is fairly resistant to infection caused my NTM, those at greatest risk are those with compromised immune systems. It's estimated that up to 50% of those with AIDS will develop NTM diseases.

Health Effects Summary

There appears to be sufficient evidence allowing a conclusion that dental waterlines are perfect for the support of microbiological life and the development of biofilms.

Some will say, "O.K., bugs are in the water … so what? I've been using this kind of water for years in my practice … is anyone getting sick or dying?" It would be reasonable to assume that the foregoing information offers some answers to this question. Further, Dr. Shannon Mills, D.D.S., U.S.A.F. Dental Corps, provides a very thoughtful answer to this quest for "proof" as follows:

"…a potential hazard does exist whenever high numbers of exogenous microorganisms with documented pathogenic potential are introduced into an anatomical region which possesses four available portals of entry (respiratory, gastrointestinal, mucous membrane, and vascular). It would certainly be desirable to have sound epidemiologic data to support all infection control practices. Unfortunately, since there is virtually no prospective epidemiology related to disease transmission in dentistry, infection control recommendations are often empirically based. Despite a paucity of epidemilogic data, the rationale for improving the quality of dental treatment water can be found in the concept of the chain of infection and in the doctrine of informed consent.

"Clinical infection control procedures focus on breaking the "chain of infection"-- which consists of sufficient numbers of potentially pathogenic organisms, a mode of transmission, a portal of entry, and a susceptible host. Most infection control measures target elimination or isolation of microbes in the clinical environment. Dental practices expend great effort and expense in accomplishing this goal as an everyday matter through the use of procedures including surface disinfection, instrument sterilization, handwashing, and antimicrobial mouthrinsing. None of theses standard practices have any greater epidemiological basis than do recommendations to improve the quality of dental water. As with the previously described practices, recommendations to improve water quality are empirical and based on the presence of potential, if epidemiologically unproved, hazards. The use of contaminated water that is unfit for human consumption for therapeutic procedures is simply inconsistent with accepted infection control principles." – "On-Line Town Meeting; Dental Unit Waterlines;" Organization for Safety & Asepsis Procedures (OSAP) – Annapolis, MD.

But I have a bottle system – that should solve these problems, right?

No. General water contamination and biofilm problems are not "solved" by using a bottle system. As mentioned earlier in this report, manufacturers of dental equipment were made aware of the design problem many years ago. In an attempt to help mitigate the problem they instituted a design that was retrofitted to current equipment. They followed the recommendation of some in the scientific community thinking that dental clinicians could simply add their own "pure" water to the system … problem solved.

In reality, the water added to bottles is often inferior to the water supplied by a municipality. Most people think "if it's bottled water, it must be fine." Not necessarily true. The microbiological quality of bottled water in surveys actually proves to be questionable at best. Even if the water is "O.K." when purchased, improper handling and storage in a dental office often leads to microbiological contamination of the remaining bulk water. "Change from city water to independent water bottle has potential to solve or exacerbate waterline contamination. Proper disinfectant & maintenance regimen determine success or failure of this option.… However, many are unaware independent water bottles can cause microbe counts to rise significantly, unless both the bottle & lines are properly & regularly disinfected with appropriate chemicals." – CRA Newsletter, September 1997

Opening and closing a water system frequently is a perfect recipe for contamination. It's like ***causing*** a water main break every day. More on this later.

What is my legal liability regarding contaminated dental waterlines?

In today's climate of class action lawsuits, mass tort litigation and general legal responsibility, the question of a dentist's liability is becoming more important. Although we've already discussed that there is currently a lack of solid epidemiological evident showing direct links to disease, infection and subsequent medical maladies, experts in the area of law feel there is reason for concern.

Opportunities for legal action emerge in several ways. One is the discovery of new scientific knowledge relating to known or perceived health hazards. One needs only to look at the issues of smoking, second hand smoke, breast implants, etc. to get a glimpse of how such issues take wings. Some believe that the dental waterline situation offers a perfect formula for mass tort litigation and class action law suits. The number of people exposed to opportunistic microbial pathogens during regular trips to their dentist is enormous.

"All of the signs are present to indicate that contamination of dental unit water may become the next hot area of mass tort litigation: a nearly unlimited pool of allegedly "injured" plaintiffs, scientific literature documenting the potential health risk, emerging government regulations, and public awareness raised by popular media reports." Crane, M., Finn, L. and Wojcicki, P., Will dental unit water be the next target of mass tort litigation? *Dental Malpractice Prevention,* March 1997.

For over thirty years the dental industry has been aware, albeit to varying degrees based on available scientific information, the problems that exist with waterlines. Industry associations and governmental agencies have recently weighed-in on the issue making various policy statements and recommendations. For example, the American Dental Association (ADA) made its opinion known when it formulated its 1995 goal – "Dental unit water systems currently designed for general dental practice are incapable of delivering water of an optimal microbiologic quality. The Council recommends an ambitious and aggressive course to encourage industry and the research community to improve the design of dental equipment so that by the year 2000, water delivered to patients during nonsurgical dental procedures consistently contains no more than 200 colony forming units per milliliter (cfu/ml) of aerobic mesophilic heterotrophic bacteria at any point in time in the unfiltered output of the dental unit; this is equivalent to an existing quality assurance standard for dialysate fluid that ensures the fluid delivery systems in hemodialysis units have not been colonized by indigenous waterborne organisms."

In addition to its 1993 Infection Control Guidelines for Dentistry, The Centers for Disease Control and Prevention (CDC) issued this statement in October 1999 – "Biofilms are microscopic communities consisting primarily of naturally occurring water bacteria and fungi that form thin layers on virtually all surfaces (including dental water delivery systems) that remain in contact with water. The presence of biofilms in dental unit waterlines has been well established. As a result of biofilm formation, relatively high numbers of common water bacteria can be found in some dental water systems. To date, however, scientific evidence indicates there is little risk of significant adverse health effects due to contact with water from a dental unit. Nonetheless, exposing patients or dental personnel to water of uncertain microbiological quality is not consistent with universally accepted infection control principles."

The Organization for Safety & Asepsis Procedures (OSAP) has stated, "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. …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."

In 2001, OSAP added new language relative to dental waterline issues – "The presence of large numbers of potentially pathogenic microorganisms in water used for dental treatment justifies the implementation of scientifically validated treatment protocols for control of microbial contamination in dental unit waterlines. …While the panel confirmed that bacteria with the potential to cause disease were present in dental water systems, there was no scientific evidence suggesting an immediate public health crisis. Nevertheless, it was clear that the quality of water used in dental treatment should be improved. The panel was unanimous in agreeing that water used for dental treatment should meet or exceed the standards set for drinking water."

The waterline contamination issue will most likely relate to two main areas in law – standard of care and informed consent. All the above scientific data and statements made by industry and government establish a "standard of care." The problem with dental waterlines has been known for a reasonable period of time (30 years) and possible remedies have been suggested by "authorities." Failing to make efforts to meet at least a minimum standard of care may place a practitioner at greater risk for legal liability.

"Informed consent" is a person's understanding of a full disclosure of events, procedures, etc. relative to risks involved with something, for example, medical or dental procedures. "This brings us to the issue of informed consent. Healthcare providers have an obligation to assure the safety of patients entrusted to their care by providing the safest possible clinical environment. As our knowledge of the potential hazards present in the clinical environment has changed, so have our practices. All healthcare workers are obligated to inform patients of potential risks associated with dental treatment. A corollary to this principle is that we should not perform procedures—even those with minimal documented risks—for which the patient is unlikely to give informed consent. Would most patients willingly accept treatment with water which does not remotely approximate accepted microbiologic standards for drinking water?" – Dr. Shannon Mills, D.D.S., U.S.A.F. Dental Corps; "On-Line Town Meeting; Dental Unit Waterlines;" Organization for Safety & Asepsis Procedures (OSAP) – Annapolis, MD.

It would appear that a dental professional who makes no attempt to adopt at least a minimum standard of care and/or fails to inform patients of potential risks associated with procedures that involve exposure to contaminated water will be legally vulnerable.

"Dentists can no longer pretend there is only a theoretical problem. Now that the state of the art has illuminated dental water contamination as a potential health risk, dentists must acknowledge the problem, stay abreast of the rapidly evolving standard of care, and do their best to comply with the standard of care in daily practice. … If one of your patients becomes ill as a result of exposure to a pathogen or bacteria that is later found in your dental unit water, you are at risk of being held responsible for your patient's illness and associated compensatory damages." – Crane, M., Finn, L. and Wojcicki, P., Dental Unit Water Contamination - What you need to know to minimize your liability risk. Dental Malpractice Prevention, April 1997.

Will federal or state agencies create new laws or stronger policies regarding waterline quality?

CDC's 1993 *Infection Control Guidelines for Dentistry* report is currently being updated and will contain more specific guidance for dental unit waterlines. It is not known if it will contain anything beyond new guidelines and recommendations.

The ADA favors a voluntary goal and strongly opposes any effort to turn a scientific goal into a legal dictate. The EPA, OSHA, National Institutes of Health (NIH) and many state regulatory boards are watching this situation closely. California is the only state we are aware of that has had specific legislation proposed regarding the waterline problem.

What about backflow prevention devices in the dental office?

The issue of backflow prevention in the dental office has been a topic of particular interest over the past few years. Some health departments require expensive backflow prevention valves at the main service entrance to the building *and* in each operatory. Some accept one at the main entrance *or* protection in each operatory. Others are not requiring any backflow prevention valves. The following information comes directly from the January 2002 update of an *Infection Control Fact Sheet* published by the CDC on the topic of backflow prevention in the dental office.

The Centers for Disease Control and Prevention (CDC) has been asked by the American Dental Association (ADA), state and local health departments, and local water regulators to provide guidance and scientific information regarding the risk of contamination from cross-connections from the dental operative unit. The dental operative unit is a medical device at each dental chair through which water and compressed air flow during dental procedures. Cross-connections are the links through which contaminated materials may enter a potable water supply system when the pressure of the polluted source exceeds the pressure of the potable source (e.g., during a water main break).

What are backflow prevention devices? Backflow prevention devices can be used to prevent back-siphonage of contaminated fluids into the public water supply and are regulated by the health authority or the plumbing-code enforcement agencies having jurisdiction. (Note: Anti-retraction valves, used to prevent aspiration of patient materials into some dental handpieces and waterlines, are regulated by the Food and Drug Administration (FDA) and are not considered backflow prevention devices.)

Is there a risk of contamination of public water supplies from cross-connections in dental operative units? In some locations water regulators have required dental offices to install backflow prevention devices at the service connection or on individual dental operative units. Many of these requirements appear to be based on two assumptions. First, if a sudden drop in water pressure occurs, oral fluids may be aspirated from a patient's mouth into cross-connected water systems. Second, if aspiration does occur, it may result in a significant risk of transmission of blood-borne viruses from an infected patient to other patients or to persons who are using the same water system. Regulatory interventions requiring the installation of complex backflow prevention devices in certain dental offices are based on the conclusion that a high degree of hazard of contamination exists. Available science suggests, however, that there is an extremely low risk of such contamination of public water supplies from cross-connections in dental operative units.

Where are cross-connections located in dental operative units? Possible sites for cross-connection in the dental operative unit are the cuspidor, high-speed handpiece, and air/water syringe. Today, most dental offices do not use cuspidors and those that are currently manufactured include an air-gap, which prevents backflow. Although a cross-connection is inherent in the design of the high-speed handpiece and air and water syringe, this cross-connection should be considered as very low risk. Both of these devices must have water to operate properly and, when in use, are observed continually by the dentist or hygienist. If water flow is disrupted for any reason, the dental worker would discontinue use of the device. Furthermore, in the unlikely event that a sudden drop in water pressure caused backflow to occur, the volume of aspirated fluid would be minuscule.

Can blood-borne viruses (e.g., HIV, hepatitis B) be transmitted through water? One concern expressed during meetings with local water regulators is the possibility of contamination of public water supplies with blood-borne viruses such as human immunodeficiency virus (HIV)--the virus that causes acquired immune deficiency syndrome (AIDS). Scientific evidence indicates, however, that the route of transmission of blood-borne viruses is through intimate contact with blood or other potentially infectious body fluids. Transmission of blood-borne diseases has not been reported through the use of any type of water source and is considered highly unlikely. Unlike bacteria or fungi, viruses are unable to reproduce outside a living host, and any virus introduced into a water source would be greatly diluted and would probably become noninfectious. Because the hepatitis B virus (HBV), another blood-borne virus, is found in much higher concentrations in blood than is HIV, HBV is considered a more infectious agent. Studies show that the risk of transmission of HBV in sewage and other water is very low, thus, the risk of HIV transmission would be even less.

For a blood-borne infection to be transmitted, four conditions, known as the "chain of infection," must be present:

- a susceptible host, or a person who is not immune
- an opening through which the microorganism may enter the host
- a microorganism that causes disease
- sufficient numbers of the organism to cause infection.

The chance of all of these events happening in sequence represents the "risk of infection." Any break in one or more of these "links" in the chain would effectively prevent infection. This information strongly suggests that the risk of transmission of a blood-borne disease through contaminated water supplies is very low.

Is there risk of contamination from cross-connections in dental operative units? Although a theoretical possibility of contamination from cross-connections from dental operative units does exist, available scientific evidence strongly implies that this risk is nearly zero. Installation of backflow prevention devices, when required, should be consistent with this very low degree of hazard. These suggestions are based on the following:

- HIV is not transmitted by water.
- Published evidence of a public health risk due to cross-connections in the dental operative unit does not currently exist.
- The American Water Works Association (AWWA) statement of policy recommends that the installation of backflow prevention devices be consistent with the degree of hazard resulting from cross-connections.
- Increasingly, dentists are using self-contained dental operative unit water systems that are not connected to the public water supply.

In addition, the manufacturers' current infection control recommendations and directions for maintenance of each dental operative unit should be followed. The CDC's Division of Oral Health will continue to assess scientific information related to the quality of dental operative unit water and the safety of patient care delivery.

Background information on microorganisms.

In 1665, Englishman Robert Hooke first described what he named "little boxes" seen through his crude microscope marked the beginning of "cell theory" – the theory that all living things are composed of cells. Italian Francesco Redi used meat and maggots in 1668 to help disprove the theory of spontaneous generation. Dutchman Antoni van Leeuwenhoek described what he called "animalcules" to the Royal Society beginning in 1673 through single lens microscope. In 1745 John Needham noticed that boiled solutions soon had substantial growth on their surface if not covered and in 1765 Lazzaro Spallanzani hypothesized organisms from the air had entered Needham's solutions. Laurent Lavoisier determined that oxygen is important to microbial life and German Rudolf Virchow developed the concept of "biogenesis," the idea that living cells can only come from other living cells. The period 1857 – 1914 has been named the Golden Age of Microbiology due to the discoveries made, learning many of the causes and cures for disease, development of vaccines and surgical techniques. And, in 1861, Frenchman Louis Pasteur demonstrated that microorganisms are in the air and can contaminate even sterile solutions. The contributions made by all of these individuals from the past were the beginning of what we know today as "aseptic" techniques.

The major groups of microorganisms are as follows:

- **BACTERIA** (procaryotes) are simple, single cell organisms whose genetic material is not enclosed within a membrane. They exist in many shapes including cocci (spherical), bacillus (rods), spiral (curved), squares and even star shapes. Most have cell walls and generally reproduce by binary fission or splitting. They eat mostly organic chemicals derived from other dead or living organisms but can also survive on inorganic substances. Some are even photosynthetic. Many bacteria move through fluids by use of a tail-like appendage called a **flagellum**. The following is a list of pathogenic and opportunistic bacteria that can be found in drinking water. Many species can be found in dental waterlines including *Mycobacterium, Vibrio, Salmonella, Heliobacter, Yersinia, Leptospira, Escherichia, Shigella, Francisella, Campylobacter, Flavobacterium, Pseudomonas, Klebsiella, Legionella, Aeromonas* and *Streptococcus.*
- **FUNGI** (eucaryotes) are organisms whose cells have the genetic material surrounded by a nuclear membrane. They have species that are both single and multi-cellular. Examples of large, plantlike fungi are mushrooms. Small, single cell fungi are yeasts and are somewhat larger than bacteria. The most common fungi are molds. Fungi are not mobile and obtain their nourishment by absorbing organic materials from their environment including soil, water, tissue, animals or their plant host. Examples of fungi of importance in dental waterlines are species of *Aspergillus* and *Penicillium*.
- **PROTOZOA** (eucaryotes) are unicellular organisms that are characterized by their locomotion. Ameoba move by use of small lobes called pseudopods. Others have long, whip-like tails called **flagella** like some bacteria. Others have hundreds of short hair-like structures called **cilia** covering their outer body. They exist in a variety of shapes and can live by themselves or as parasites. They eat organic substances from their environment or a host. Examples of important protozoans in dental waterlines are species

of *Microsporidium, Giardi* and *Cryptosporidium*, the latter being discussed in more detail later.

- **ALGAE, VIRUSES and HELMINTHS** are other major groups of microorganisms but will not be discussed here since they are not typically a concern relative to dental waterline issues.

Microorganisms are extremely small and are usually measured in micrometers (m), also known as a micron. A micron is 1/1,000,000 of a meter or 10^{-6} m. Most bacteria and protozoa will range in size from 0.2 – 1.0 m wide and can be as long as 25 m as in the case of a very large organism like *Giardia*. As a comparison, the diameter of a human hair is about 50 m.

Bacteria are also classified by the methods they use to live, grow and metabolize food (autotrophs, chemotrophs, etc.). The American Dental Association's formal statement regarding waterlines refers to "aerobic, mesophilic, heterotrophic bacteria." **Aerobic** organisms are microbes that require oxygen for growth to occur. **Mesophilic** refers to organisms that grow best in moderate temperature water (10˚ C - 50˚ C). Unfortunately, the temperature of dental waterlines falls nicely in this range providing optimal conditions for rapid growth. **Heterotrophic** (also called organotrophic) organisms require an organic carbon source for nourishment.

A **pathogenic** organism is one that directly causes diseases. An **opportunistic pathogen** is one that doesn't ordinarily cause disease but can do so under certain circumstances. For example, *Escherichia coli* is normally harmless when in the large intestine. However, if it finds its way to another part of the body (bladder, lung, stomach, etc.), it may cause infection and abscesses possibly resulting in death. Another example may be the presence of an organism in and individual who becomes immunocompromised in some way. In a weakened person, the microbe seizes the opportunity to go beyond a state of symbiosis due to a temporary or permanent weakness in the immune system. Examples of immune weakened conditions include the very young, the very old, a smoker, someone with a cold, flu, cancer, undergoing chemotherapy, AIDS, etc.

Coliforms and heterotrophic organisms in drinking water.

Water is supplied to homes, businesses and dental delivery units from a variety of sources including direct connection to a municipal water authority, community water system, well water or independent water bottle system. The chemical and microbiological quality of each water source will vary making quality control an issue. Almost regardless of the source, microbial life is ubiquitous and will eventually find its way into every system.

Most municipal waters in the United States, Canada, Mexico and other countries are treated with **chlorine** or a combination of chlorine and ammonia known as **chloramine**. The goal is to provide a continuous residual of the chemical in the water to control microbial growth. The residual amount varies but is required to be present for two basic reasons. As water leaves the treatment plant it has a higher residual and is free of "**coliform**" bacteria. However, seepage of ground water into the finished water supply through a crack in piping may recontaminate the water. The residual chlorine in the lines may be able to continue "killing" miles away from the treatment facility thereby protecting users. Another reason for residual chemicals at a user point, say a kitchen faucet, is to be able to determine "**bio demand**." Since the presence of pathogenic organisms and organics would place a continued demand on the residual chlorine, a measurable residual presumes that the water is microbiologically safe since it hasn't all been used up.

Tests for water purity and safety used today are aimed at detecting particular "indicator organisms." There are several criteria for an indicator organism, the most important aspect being that the microbe is consistently present in human feces in substantial numbers so that its detection is a good indication that human wastes are entering the water. The indicator organisms must also be detectable by simple tests. In the United States, the usual indicator organisms are the coliform bacteria. Coliforms are defined as aerobic or facultatively anaerobic, gram-negative, non-endospore-forming, rod-shaped bacteria that ferment lactose to form gas within 48 hours of being placed in lactose broth at 35˚ C. *(From "Microbiology – An Introduction, Sixth Edition" by Tortura, Funke and Case)*

The predominant fecal coliform is ***E. coli***, which constitutes a large proportion of the human intestinal population. Basically, if there are no coliforms found the water it is considered to be microbiologically safe for use.

Virtually all water supplies have heterotrophic organisms present at some time. Heterotrophic plate counts for a city water supply can range from 0 cfu/ml to 500 cfu/ml or more. Those levels can, and often do, change daily. Fortunately, the coliforms are very easy to kill with low levels of chlorine or other disinfectants. Most heterotrophs, however, are able to survive despite the chlorine residual level. They usually present no health concern to normal individuals who are used to those particular species but are, as we mentioned earlier, opportunistic.

For example, many people who travel to a city in a different country will often react to the different heterotrophs that may be present in that water. This is true even though that city also treats its water with chlorine. It's simply a matter of what one is used to. They may experience several days of diarrhea and/or stomach upset until their immune system responds to bring them back to normal.

Protozoans found in water supplies.

Although there are many protozoans found in drinking water and dental waterlines, there are several that have gained certain notoriety over the past 20 years. ***Giardia lamblia*** is a single-celled microscopic parasite that lives in the intestine of people and animals and causes a diarrheal disease known as giardiasis. *Giardia* has become one of the most common causes of waterborne disease in humans in the United States and around the world. Several community-wide outbreaks of giardiasis have been linked to drinking municipal water or recreational water contaminated with *Giardia*. The parasite is found in drinking and recreational waters and is passed in the stool of an infected person or animal. It's protected by an outer shell that allows it to survive outside the body and in the environment for long periods of time. It's extremely difficult to kill with chlorination and other methods due to its ability to enter an encysted state.

Cryptosporidiosis is a diarrheal disease caused by the microscopic parasite ***Cryptosporidium parvum***. It can live in the intestine of humans and animals and is passed in the stool of an infected person or animal. Like *Giardia,* it too is protected by an outer shell that allows it to survive outside the body for long periods of time and makes it very resistant to chlorine disinfection. Persons with weakened immune systems are at risk for more serious disease. Symptoms may be severe and could lead to serious or life-threatening illness. Examples of persons with weakened immune systems include those with HIV/AIDS, cancer and transplant patients who are taking certain immunosuppressive drugs, and those with inherited diseases that affect the immune system. The largest outbreak of waterborne disease in the United States occurred in Milwaukee, Wisconsin in 1993. Over 400,000 persons were infected by *Cryptosporidium* resulting in the hospitalization of 4,000 and the deaths of at least 50 people.

How dental waterlines become fouled with biofilms and other contaminants.

It's estimated that 99% of bacteria in nature aggregate as biofilms which makes them very important to study and understand. The creation of biofilms is basically multi-step process involving **attachment, colonization** and **growth**. Creating suitable conditions for biofilm development actually begins the instant water enters the dental tubing. Common organic particles from the water are adsorbed onto the inner surface of the tubing forming a **conditioning layer**.

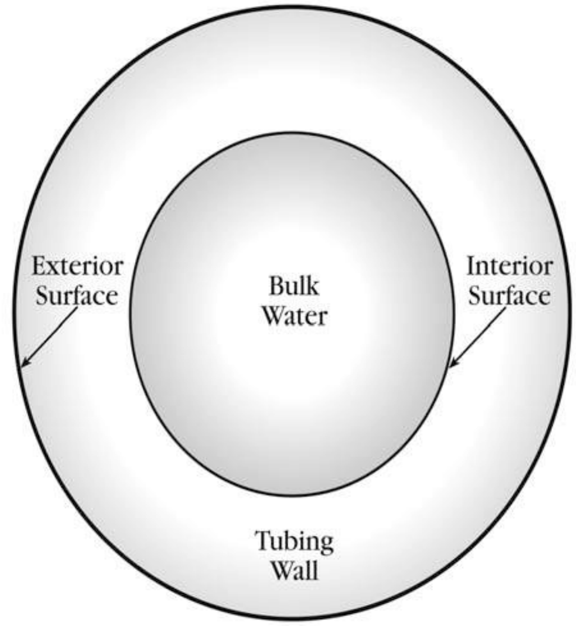

Figure 1. Clean dental waterline tubing. No biofilms or free-floating organisms present.

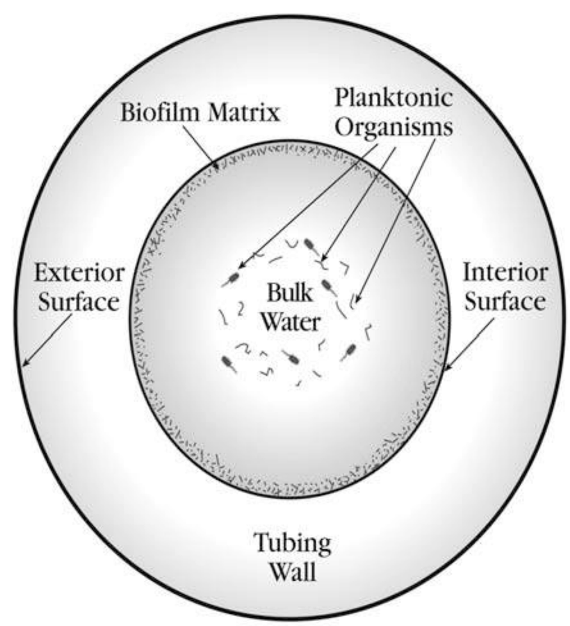

Figure 2. Contaminated dental waterline. Biofilm on interior surface with abundant free-floating organisms.

This microscopic film helps to neutralize any electrical charges produced by the tubing that could be unfriendly to bacteria. Although bacteria can colonize virtually any type of tubing or piping, their job is a little easier in plastic and rubber types over metals – especially copper.

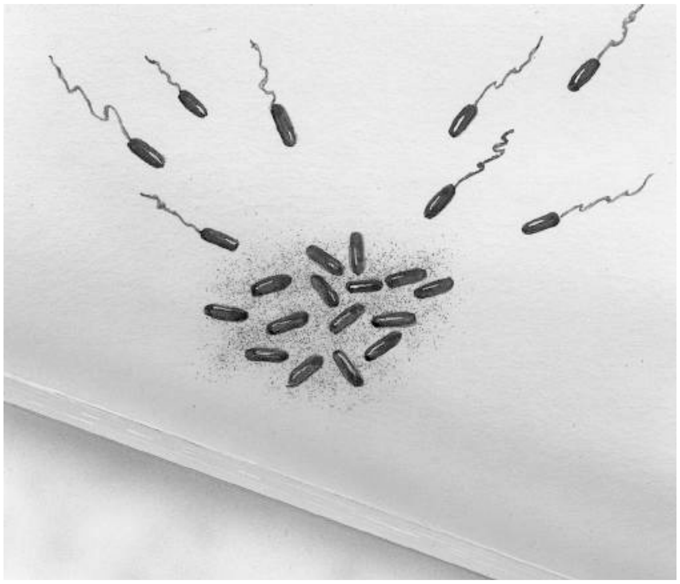

Figure 3. Organisms begin to form conditioning layer on interior tubing wall.

Planktonic (free floating and swimming) bacteria enter the small diameter tubing moving through the bulk water in various ways. In large part, these are the heterotrophic organisms that we just discussed – those that coexist with chlorine and disinfectant chemicals in a city water system. Other organisms may enter the tubing network through "suckback" from a patient, originate in dead legs or be introduced through a bottle system. As discussed earlier, some bacteria have long tail-like structures called **flagella** while others have tiny cellular extensions on their body that move in a wave-like manner called **cilia**. **Figure 3** shows planktonic organisms approaching the **boundary layer** which is the quiet zone at the wall of the tubing where the velocity of the water falls to near zero due to the **laminar flow** discussed earlier. Here they form an initial **reversible attachment** by means of tiny hair-like appendages called **fimbriae.**

The bacteria are attracted to the surface due to the presence of the organics previously adsorbed onto the tubing that provide nourishment. Many of the bacteria will make **irreversible attachments** when numerous fimbriae attach to the tubing wall. At this point they become **sessile** (attached) and are held firmly in place as they begin to secrete **extracellular biopolymers**, also called **slime layer** or **glycocalyx**. The glycocalyx consists mostly of **polysaccharides** and water. **Figure 4** shows a significant buildup of bacteria and gelatinous

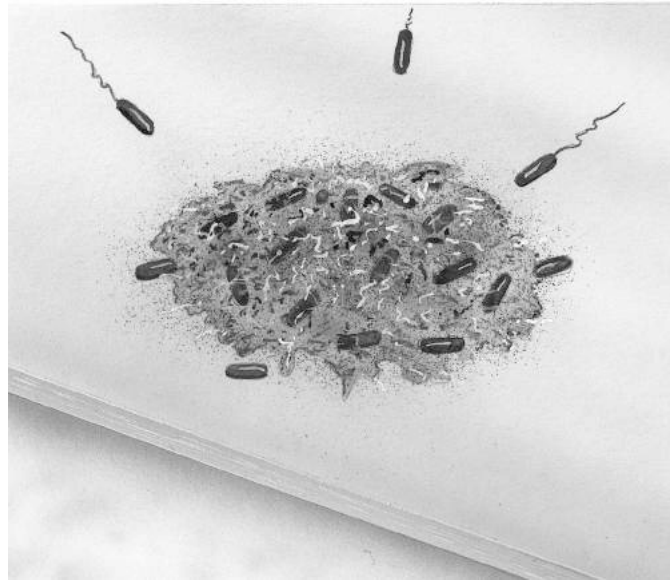

Figure 4. Organisms begin to make irreversible attachments to interior surfaces of waterline tubing.

glycocalyx at the tubing surface – the building block for a complex biofilm.

Other chemical and physical factors in the water are going to affect the speed and successful development of a biofilm. For example, **calcium** and **magnesium** (hardness) in the water can react electrostatically with the functional groups on the polysaccharides that result in **bridging** and **crosslinking** that helps stabilize the biofilm, much like adding rebar to concrete. This crosslinked, webbed matrix helps to harden the film making it very difficult to pentrate with cleaners and disinfectants.

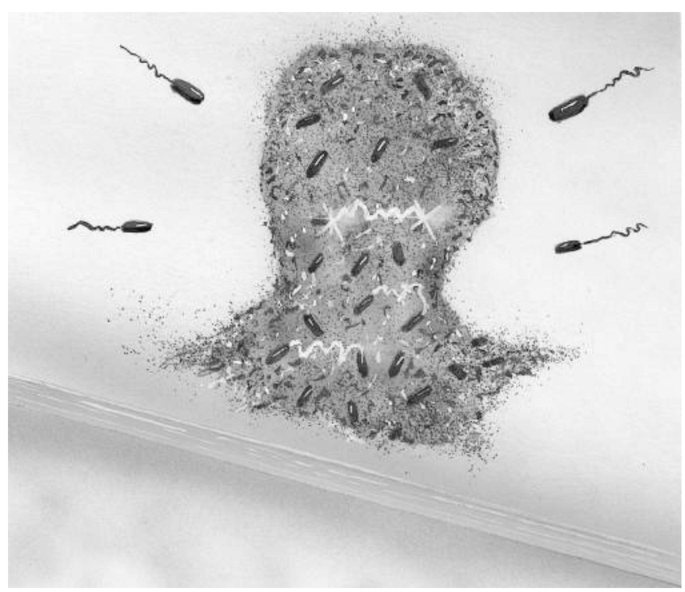

Figure 5. Mushroom-like biofilm towers begin to form.

As the biofilm matures, as shown in **Figure 5**, it starts to form mushroom-like towers that extend further away from the tubing surface. The tower begins to gather debris from the water that can later cause complete plugging of the tubing. Secondary organisms are also snagged by or purposely join the biofilm structure. They are nourished, in part, by the waste products of the primary colonizers. Their wastes then become nutrients for yet other organisms that may join the community.

If the flow rate through the tubing is rapidly increased and a "tower" is in the flow path, all or a part of the film can be dislodged and swept away. This can cause a huge temporary increase in the measurable colony counts and a slimy discharge might be seen emerging from the tubing appliance. Bits of the broken biofilm matrix will settle onto the tubing surface downstream of the break and re-establish another tower. It's also been discovered that when the remaining portion of a broken biofilm senses **shearing forces**, it can change the chemical make-up of the tower giving it more flex and strength to resist future high flow conditions.

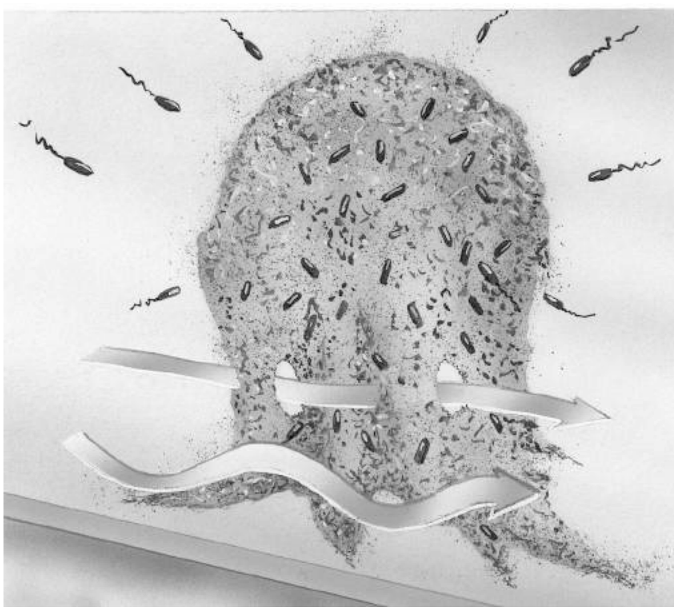

Figure 6. Maturing biofilm begins to form channels and continues to strengthen.

Figure 6 shows an even more mature biofilm tower that has developed height, strength and channels throughout. Z. Lewandowski of the Center for Biofilm Engineering at Montana State University in Bozeman, MT, has described mass transport characteristics within biofilms. Water freely moving in and around the biofilm towers induces convective mass transfer of dissolved and particulate substances. Experiments using microscopy and velocity meters have revealed double flow fields existing above and below the biofilm surface that interact to control the hydrodynamics in the biofilm region. This highly complex community is firmly attached to the tubing surface and attracts an even more diverse population of bacteria, fungi and protozoans that are living cooperatively. According to William Costerton, also with of the Center for Biofilm Engineering at Montana State University in Bozeman, MT, and others, it's estimated that sessile organisms living in a biofilm are from 1,000 to 1,500 times more resistant to disinfectants and antibiotics than their planktonic counterparts due to the survival benefits bestowed upon organisms that reside in biofilm communities.

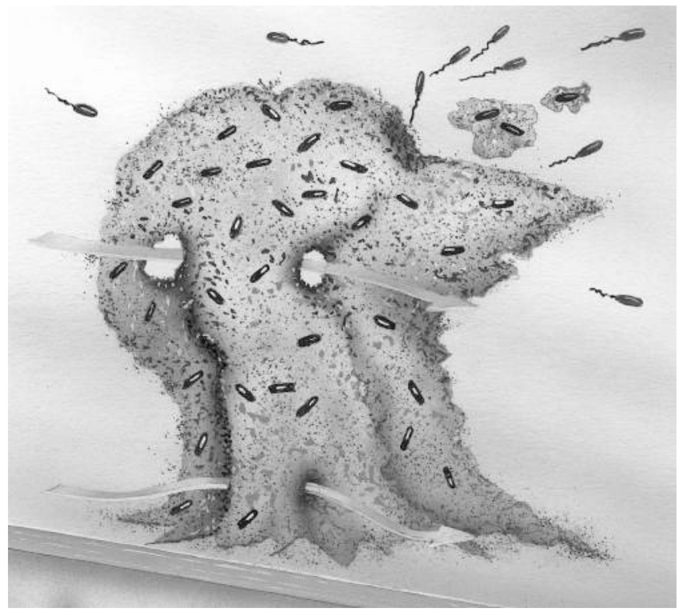

Figure 7. Massive biofilm tower becomes extremely resistant to attack by cleaners, disinfectants and antiboitics. Pioneer organisms and pieces of biofilm break loose and flow to other locations within the system.

Given proper time, temperature, pH and food supplies, a biofilm can grow to massive size and sophistication as shown in **Figure 7**. Here the water channels are better developed that assist in moving nutrients, metabolic wastes and communication signals. A phenomenon known as **quorum sensing** is believed to be the "communication system" used by the biofilm community. Biofilm and its slime was earlier thought to be a random mass of organic sludge that simply formed as a result of organic buildup as individual cells lyse and deposit their remains. However, due to the use of high end technologies like magnetic resonance imaging, scanning electron and confocal scanning laser microscopy along with brilliant discoveries made by talented scientists around the world, it's now known that this organic "goo" is really a sophisticated, symbiotic community of organisms with cell-to-cell communications networks that can respond in a matter of seconds to warnings of impending danger to the colony sent by fellow inhabitants upstream. Acylated homoserine lactones (AHLs) are the chemical sig-

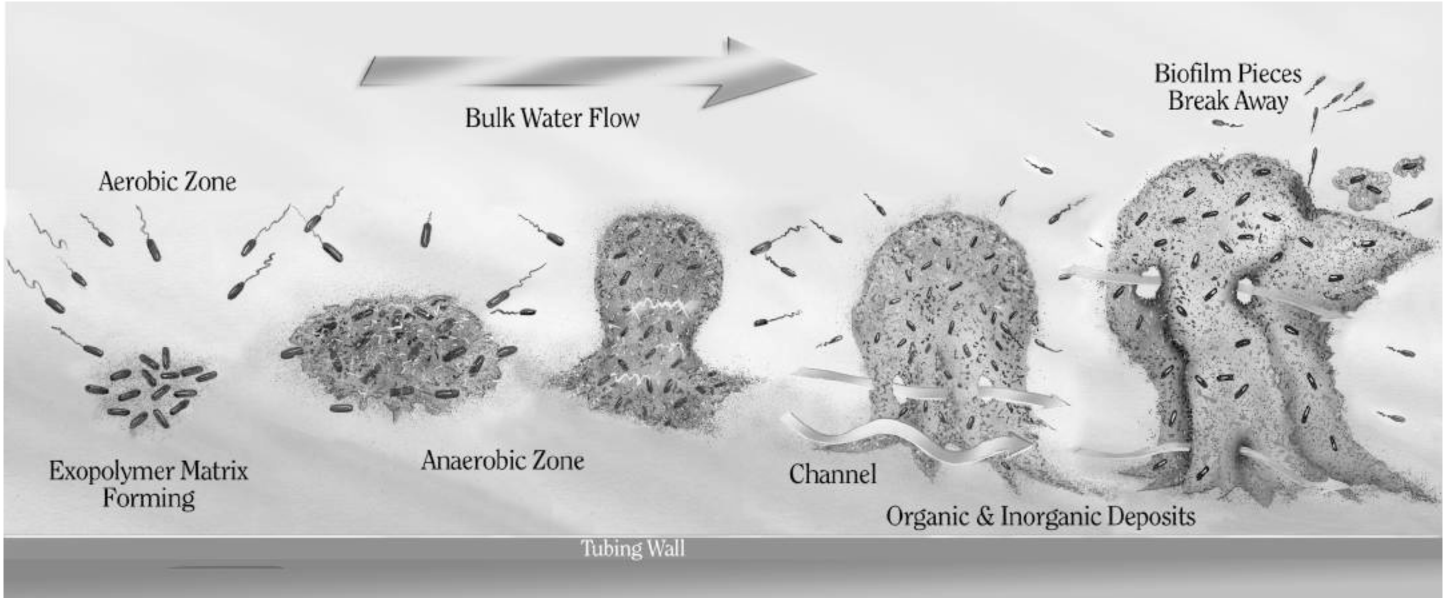

Figure 7. Evolution and progressive maturation of biofilm community. Being highly complex in nature, biofilms can have both aerobic and anaerobic zones along with nutrient and waste transport channels, communications networks and inherent defense mechanisms. *(Illustration based on information from the Center for Biofilm Engineering, Tortura, Funke, Case and others)*

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nals that do everything from mediate population density to manipulation of gene expression. This gene transfer can convert previously opportunistic organisms into highly virulent pathogens.

These signals are presumed to attach to the DNA and can instruct individual cells and organisms to activate, de-activate, become encysted, etc. As in the case of infections caused by organisms, it appears they respond to quorum signals as conditions become favorable and are able to produce and release toxins that cause inflammation and other problems for their host. In the case of biofilm development in dental waterlines, this amazing ability for the "lowest" forms of life to generate what could be described as intelligent or instinctual activities and communications makes eradication very difficult. "Dr. Mangan noted that biofilms, accumulated bacteria on a hard surface, are important in about 80 percent of all infections and in oral and other medical diseases. When they accumulate in the water lines of dental laboratories, biofilms can pose a significant health hazard. They are interesting biologically because they are remarkably difficult to treat with antibiotics, are protected from many of a host's natural defenses, can induce bacteria to assume a different and more virulent phenotype, and offer an opportunity for transferring genes between and among communicating bacteria." – "Minutes for the National Advisory Dental Research Council;" September 9, 1997; National Institutes of Health (NIH) – Bethesda, MD.

Resistant Organisms & "Super Bugs."

Resistance of organisms to antimicrobials, disinfectants and antibiotics is becoming a very serious problem. According to Dr. Harold Slavkin, D.D.S., Director of the National Institute of Dental Research, cholera, measles and other diseases have been virtually wiped out around the globe yet new infections like Legionnaire's disease, Lyme disease, Hauntaviruses, Ebola, AIDS and others have also spread. Tuberculosis and other bacterial infections are emerging in new drug-resistant strains. As just described with quorum sensing and cellular communciations, all types of organisms seem to be able to **mutate** based upon environmental conditions for the sake of survival.

According to an article in the October 25, 2001, issue of *Nature*, University of Iowa scientists and their collaborators at Harvard, Northwestern and the University of Washington, used a technology called **microarray analysis** to identify subsets of genes in bacteria that behave differently when the organism exists within a biofilm. Out of about 5,500 genes in *P. aeruginosa,* it was determined that 73 of the genes have different activation patterns when the organism in a biofilm. "Because cells in biofilms are spatially fixed, antibiotics applied to the biofilm, even at very high concentrations, only gradually diffuse to distant parts of the biofilm," stated the researchers. It appears that biofilm cells are exposed to gradually increasing concentrations and, rather than being killed, have time to respond by changing genetic code.

Bacteria can become resistant to drugs and disinfectants in several ways. Some have enzymes that can destroy an active drug after it enters the bacterium. Others have the ability to remove the active ingredient from its cell before it has time to do damage. Still others can alter or bypass the biochemical pathway that the drug was designed to inhibit. Microbes have the amazing ability to quickly respond to attacks due to two major advantages. When compared to higher forms of life, they have vastly fewer genes. They can respond almost instantly changing genetic codes in each new generation that insures survival until the next change is required when they will be able to respond once again. Another is the simple fact that they replicate so fast. In some organisms, multiple generations can be produced in an hour. For example, millions of organisms can be killed by a particular agent but just one survivor can continue to refine genetic code passing its survival ability to progeny.

Microbes that were successfully arrested in the past are building resistance due to exposure to various antimicrobials and returning in mutant forms. Several potential causes for this phenomenon, at least in the area of antibiotics, include the dispensing of antibiotics without specific clinical justification, patients not adhering to proper dosing and the indiscriminant use of antibiotics in the production of plants and livestock products for foods. Further, there are a confounding number of products that contain antimicrobial agents including fabrics, plastics, soaps, vegetable rinses, toys, etc. Detectable levels of antibiotics are even being seen in ground waters due to the movement of antibiotic residuals through the hydrologic cycle. Drugs from the waste of human and animal antibiotic users, production disposal and other waste methods are making all varieties of antibiotics available throughout the environment in diluted amounts which help environmental organisms build resistance as they change aspects of their genetic code.

Resistant and mutated organisms are causing tremendous problems throughout the world. Hospitals and other health care facilities are facing increasing numbers of resistant organisms resulting in more nosocomial infections. Strains of *Staphylococcus aureus* resistant to all antibiotics except vancomycin are endemic in health care facilities according to Slavkin. Until 1989, vancomycin resistance had not been reported in U.S. hospitals but by 1993, more than 10% of reported nosocomial infections of enterococci were resistant. Further, *Streptococcus pneumoniae* caused thousands of cases of bacteremia, pneumonia and meningitis, and a million cases of otitus media each year. About 30% of all *Streptococcus pneumoniae* isolates are resistant to penicillin, the primary drug for treating such infections.

Drug and disinfectant "resistance" may not seem to have relevance in the study of dental waterline contamination, however, the "harmless" opportunistic heterotrophs that are potentially present in huge numbers in the waterline biofilms could quite possibly be resistant mutants that can present an even greater danger to patients and staff than the same species did just a few years ago.

Other water contaminants found in drinking water and dental waterlines.

Chlorine is added to water in order to destroy pathogenic organisms like the coliform *E. coli*. The residual level needs to be reasonably high to ensure continued killing action as water moves throughout the piping and transmission system. As already discussed, however, many of the heterotrophs and protozoans are not killed or inactivated by these levels of chlorine. Low-level chlorine residuals in a dental waterline are virtually useless. If it can't deal with the secondary heterotrophs, it's certainly not going to have any beneficial effect on biofilms and related microbes.

Although chlorine does a good job of controlling coliforms, one of the negative aspects of chlorine residuals in water is the resulting creation of **trihalomethanes (THMs)**. THMs are formed as the residual chlorine combines with organics to form these carcinogenic compounds. In addition to the tannins, fulvic and humic acids common to water, especially water from reservoirs and shallow wells, waterline biofilms provide a huge helping of organic compounds.

Chloramines are also water treatment disinfectants that are basically created by combining chlorine and ammonia. Its benefits are that the residuals don't create THMs and it's considered to be a stronger oxidant. Many people and aquatic life are very sensitive to chloramines since it can cause irritation to the eyes and nasal membranes. Again, the residual amounts in municipal water supplies are insufficient to kill or inactivate most heterotrophs and are totally ineffective against biofilms.

Water **hardness** is derived from calcium and magnesium minerals that have been dissolved into water beneath the earth's surface. These minerals are found in limestone deposits and are the primary source of hard water. When the minerals dissolve, they become electrically charged particles call ions. The amount of hardness in any given water is dependent upon the amount of calcium and magnesium minerals present, the pH of the water and the length of time the water stays in contact with them. The degree of hardness varies greatly from region to region but is common in over 85% of the U.S. Hardness is measured in Grains per Gallon (gpg). Concentrations over 3.0 gpg are considered "hard" and will cause various problems.

In dental waterlines, the presence of calcium and magnesium is problematic for two main reasons. As we discussed earlier, as organisms create biofilms, they utilize calcium and magnesium to help create crosslinks and bridges that strengthen the biofilm structure. Another problem is that of scaling. When hardness ions come in contact with metal components of the system, like distribution blocks, fittings, etc., the calcium and magnesium tend to build up which can cause restrictions and even complete blockage of the tubing network. This usually results in a service call for cleaning or costly replacement of the affected parts.

Heavy metals including mercury, lead, arsenic, barium, chromium, cadmium and others are sometimes present in municipal, community and private well waters in varying amounts. Not only are these contaminants dangerous to human health due to their nature to accumulate in the body, they are also food for certain organisms and additional building blocks for the biofilm structures.

Iron & Manganese are very common in rocks and soil. These compounds are easily leached into the water supply after coming into contact with ground water, particularly acidic water. Iron and manganese are well known for depositing red, orange and/or black stains on plumbing fixtures, laundry, and anything the water touches. These water constituents are measured by quality water testing and quantified in Parts per Million (ppm) or Milligrams per Liter (mg/l). The limit for iron is 0.3 mg/l and for manganese, 0.05 mg/l. Serious damage to the entire water system may result if these compounds exceed the maximum contamination limit. Most municipal and community water systems attempt to remove iron and manganese before distribution but can't always remove it completely. They will often feed a chemical like sodium hexametasulfate that will bind the minerals so they stay in suspension and will not cause staining and plugging problems. However, some microorganisms found in the dental waterline biofilm community can breakdown the compound and utilize the iron and manganese as a food source.

Tannins & Humic Acid are naturally occurring compounds that enter a water supply through contact with decaying leaves and various other types of vegetation. Some of the problems they cause can be slight odors, odd tastes, yellow color and possible staining of fixtures and clothing. These organic compounds tend to "coat" certain surfaces with a film, are available to react with chlorine residuals to create THMs and also provide additional food for microorganisms in the waterline.

Turbidity & Color can originate from any number of sources. Obvious is the presence of light-to-heavy color or a fine "grit" in the water. Clay, sand and silt can be a source for turbidity, or the presence of tiny particles. These particles can cause serious damage to the moving parts of appliances and plug tiny openings and tubing found in dental units, handpieces, air/water syringes, etc. The colors can cause staining and are usually derived from organic sources that, again, provide potential food sources for organisms. As mentioned earlier, particulate in the bulk water stream can also be trapped in the biofilm causing potential line or port plugging or simply become additional food and building blocks for the matrix.

Herbicides, Insecticides & Organic Solvents are usually found in water supplies in extremely small quantities. There have been and still are incidents of alarming quantities being found as in the case of MTBE. MTBE (methyl-t-butyl ether) is a member of a group of chemicals commonly known as fuel oxygenates. Oxygenates are added to fuel to increase its oxygen content and replaces the use of lead as an octane enhancer. It is being found in private and public water supplies nationwide and enters through cracks in pipelines, spills, emissions from marine engines into lakes and reservoirs, and to some extent from air deposition. It and the other contaminants mentioned here are carbon-based organics that are both dangerous to consume yet are a source of food sources for many microorganisms.

pH is not a "contaminant" but is what determines the alkalinity or acidity of a substance. If water is acidic, it will have values from 0 to 6.9; if alkaline, from 7.1 to 14. Water with a pH of 7 is considered "neutral." Most municipal water supplies try to keep pH levels between 6.8 and 8.0. As earlier discussed, most of the natural groundwaters throughout the U.S. contain significant levels of hardness due to the presence of calcium and magnesium. It's these minerals that dissolve in water and raise the pH to ranges usually at or above 7.0. The few portions of the country that have naturally "soft" water (lacking hardness) are the areas that also have lower pH levels and are, therefore, acidic.

Corrosion is usually associated with acidic water and can cause the release of toxic metals such as lead, zinc, copper, chromium and cadmium from pipes, plumbing fixtures and equipment. Corrosion associated with low pH can literally destroy all types of metallic plumbing and fixtures. Fixtures can have blue-green stains caused by the corrosion of copper or brass plumbing or red stains caused by the corrosion of iron plumbing. If not corrected, corrosion will eventually cause pinholes in piping and necessitate extensive equipment repairs or complete replacement.

Other problems can occur in water with a high pH. For example, when the pH exceeds 8.5, water may have an alkali taste, scale may form in pipes and equipment, the germicidal activity of chlorine is reduced, and the formation of trihalomethanes is accelerated. There are bacteria that can survive in most any pH range but the heterotrophs, unfortunately, prefer and tend to thrive in the normal municipal water range of 6.8 to 8.0.

Although there are other water contaminants found in water supplies, most will be of little or no significance in the discussion of dental waterlines. Further, it should be understood that the small amounts of chemicals and other water contaminants potentially consumed by or exposed to a dental patient during a visit have virtually no direct, negative health effects to the individual patient since the exposure is very short-term, most dentists use rubber dams, suction, etc. However, it is very important how these contaminants may:

- benefit microorganisms and support biofilms,
- cause damage to the dental unit and related equipment and,
- negatively affect the health of the dental staff as a result of daily exposure to the contaminants and the resulting chemical and biologic aerosols.

Methods for controlling biofilms.

In October 1999, the American Dental Association presented its "Statement on Dental Unit Waterlines." In this statement they suggested the following:

"At the present time, commercially available options for improving dental unit water quality are limited and will involve some additional expense. They include the use of:

- Independent water reservoirs
- Chemical treatment regimens
- Daily draining and air purging regimens
- Point-of-use filters

Preliminary data suggest that some combination of the above strategies will be necessary to control biofilm formation and to achieve the desired level of water quality."

Independent Reservoirs

Probably the most common method for dealing with dental waterline problems is the use of **independent water reservoirs**. As a matter of fact, most new dental chairs and delivery equipment come standard with such bottle reservoirs. The bottle system concept was discussed earlier in this report but bears repeating. This method uses a plastic bottle with a pick-up tube and compressed air. Water must be added manually to the bottle whenever it runs low. This is a relatively simple and "apparently" inexpensive (+/- $200 per operatory to retrofit to a dental unit) approach but has a number of issues that must be considered. Since water must be added manually, there is substantial staff time required. Also, the water supply can run out during a patient procedure. In addition, bottled water of some type must be purchased, stored and handled which becomes costly and time-consuming.

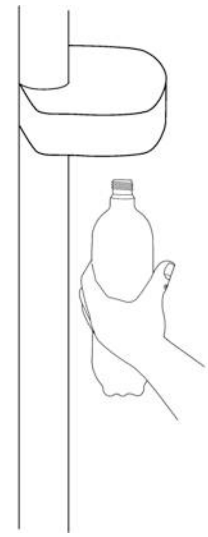

Figure 8. Typical independent bottle system now found on most new dental operatory systems as standard equipment. A concern is that they can actually exacerbate the contamination problem.

Fact is, if one is using a bottle system (opening and closing it daily) aggressive cleaning is required on a very frequent basis since each removal of the bottle for filling is analogous to a "water main break" in context of a municipal water system. Not only is the bottle and its threads exposed, so are the mating receptacle and "dip" tube. Users will often even touch the tube to start it into the bottle furthering contamination.

One of the biggest problems with this approach is determining the true microbial quality of the purchased water. It's not easily done unless purchased at a premium price from a laboratory or specialty service. Both the bulk container and the reservoir bottle can be contaminated by organisms from the atmosphere and the handler. The more often the bottles are handled the more chance there is of contamination. Once just a few organisms enter the system, colonization begins. Field service technicians will attest to the fact that unless bottle systems are aggressively maintained on a very frequent basis line fouling and high cfu counts will occur.

Tied directly to the concept of bottle systems is the need for a supply of quality water. As mentioned earlier, commercially available bottle water varies greatly in its microbiologic quality. Further, once opened, handling and storage becomes a major issue in attempting to maintain efficacy.

Distillation

Some will suggest that **distilled** water is the best quality. True, distillation does a fine job of killing and/or inactivating microorganisms, spores and even cysts. However, there are several problems associated with distillers. By design they "boil-out" inorganic contaminants. In other words, the water is converted to a gaseous state and condensed on the outlet side of the device. This means that calcium, magnesium, iron, sediment, etc. are left in the chamber and must be cleaned on a very regular basis in order to maintain a scale, contaminant-free system. Further, some distillers allow contaminants with a boiling point lower than water (e.g. some pesticides and volatile solvents) to vaporize with the water and recondense with the treated water, which means they remain in the treated water. Others, called fractional distillers, have a volatile gas vent that releases these products to the atmosphere. We've all heard that water is the "universal solvent." This means that pure H_2O is very corrosive. It does its best to dissolve anything it can to become stable. When it comes in contact with metallic components of any water system, plumbing or the dental unit it will tend to begin corroding the contact surfaces that will eventually damage or destroy the parts.

By default, distilled water requires the use of a bottle system for dental units. Normal distillers produce and store the freshly prepared water at atmospheric pressure. It must be transferred to a vessel capable of producing pressure in order to deliver it to the dental unit for use. Therefore, one is back to the problems inherent to bottle systems and their potential to exacerbate the microbiological problems as earlier described. Interestingly, microbes introduced to distilled water are often able to survive due to the fact that the aggressive water pulls organic and inorganic substances into solution from pores in the tubing and system components providing sufficient nutrients for the organisms to survive.

Reverse Osmosis

Water prepared by a process called **reverse osmosis** has also been suggested as a type of water to be used in dental units. Although reverse osmosis does do a great job removing many organic chemicals and inorganic constituents, the process does not remove everything. For instance, it will not remove chloroform (one of the THMs) without the use of an additional filter module. And, it does not remove 100 percent of most chemicals. Another problem with R/O systems is the waste of large amounts of water. Most units will discharge 50% or more of total water as waste. The membrane can develop problems from precipitate buildup and scaling. A softener must be installed ahead of the reverse osmosis unit if hard water is used or the calcium and magnesium minerals will quickly plug the membrane filter and reduce its throughput capacity. In addition, R/O membranes can experience "bio-fouling" or "microbial fouling" which is the plugging or coating of the membrane pores with microorganisms. Eventually, the system will have a reduced capacity, waste more water, become completely plugged or bacteria can "grow through."

Once R/O water is forced through the membrane, it flows to either an atmospheric or lightly pressurized storage vessel. If pressurized, the normal charge is about 10 psi, just enough to deliver it to drinking faucets. Dental units are usually set to pressures of about 40 psi. If the precharge is increased, the differential pressure drops across the membrane making filtration less efficient which decreases the water quality and wastes additional water. Unless the system is fitted with a high-pressure pump on the inlet side or a transfer booster pump on the outlet side, an R/O system would require the use of a bottle system. Also, R/O water can be of a high enough quality (lacking dissolved solids) to create corrosion and re-contamination problems.

Chemical Treatment Regimens

The only good thing about an independent bottle system is that it provides a means to deliver **chemical cleaners.** This is the second method mentioned by the ADA above. Numerous agents have been suggested but, at this writing, none have been formally approved as waterline disinfectants by the FDA or EPA. Regimen chemicals mentioned in the literature include high levels of chlorine (sodium hypochlorite NaOCl), chlorhexidine gluconate, gluteraldehyde, iodine, citric acid and chlorine dioxide. Some agents have been found effective in reducing or even eliminating planktonic bacteria counts and others do a respectable job with the biofilm as well.

However, there are several concerns with aggressive chemical regimens. One is the strength and corrosiveness of some agents that can attack metallic components of the dental delivery system. As discussed earlier, pH is a major aspect in the successful removal of bio-matter but is a serious concern for corrosion. Some of the chemicals mentioned plunge the pH into a very low acidic range while others raise it to equally corrosive high alkalinity ranges.

Other concerns involve inadvertent chemical residuals left in the waterlines that may be a health concern for patients. Daily exposure to the chemical disinfectants and aerosols is a potential concern for the dentist and clinical staff over long periods of time. And, finally, chemicals that remain in the water as irrigants during patient treatments may have a negative effect on bonding. Recent studies have shown that certain irrigants significantly reduce dentin and enamel bond strength.

System Draining and Purging

Daily draining and air purging regimens are also suggested as a method to help control biofilms. For example, the current CDC recommendation for waterlines includes the installation and proper maintenance of anti-retraction valves and thorough flushing of the dental unit waterlines at the beginning of each clinic day and after treatment of each patient. They indicate that these procedures can assist in flushing out patient material that may have entered the water lines and may reduce - at least temporarily - overnight or weekend microbial accumulation in water lines. <u>Flushing of the waterlines, however, does not appear to reduce adherent biofilm in the tubing</u>.

Some have indicated as long as 5-8 minutes for a purging regimen. From a practical standpoint, who has the time to perform such a lengthy purge on every line every morning in every operatory?

Filtration Devices

Point-of-use filters are another option currently available. Some contain iodine that elutes into the water stream. Others are located just before the handpieces and air/water syringes and contain sub-micron ceramic disks.

These sub-micron disks do an excellent job physically removing bacteria and other organisms but have a number of problems according to testing and comments from dentists who have used them. The filtration capability is so fine that they often plug with suspended solids found in the water supply – often plugging during a procedure that is highly inconvenient. They do nothing to eliminate biofilms from the system and consequently have to endure massive colony count challenges from well-developed biofilms that form ahead of the filters. They simply serve as a "last defense" in the dental unit lines.

Expensive handpiece, air/water syringe and ultrasonic scaler lines must be cut in order to retrofit the ceramic disk housing. The additional weight on the line and the potential for leaks have also been discussed as negatives for this technology. Another issue is colonization of the few inches of tubing after the ceramic element.

A very big concern is that of cost. The individual disks are rather inexpensive but due to the vast number required each year on each line of each operatory, the costs can rise into the thousands of dollars each year for replacement elements in each operatory plus staff time required to make the changes.

Other Treatment Options

Several other types of systems have also come to the market. **Ozone systems** can be very efficient at killing organisms (producing zero or near zero cfu/ml counts) but face several problems. The quality of the ozone is greatly affected by the moisture content of the air it uses to produce the ozone and should, therefore, utilize desiccants and/or electric dryers. Since ozone is very corrosive, there is a concern for long-term use and potential degradation of parts within the dental system. Ozone does remain in the water at least a temporarily but maintaining an even residual is difficult to maintain. If the residual is too high, corrosion is certain. It it's too low, it looses its killing potential.
An electrical power source must also be available and the quality of the water used must be high since the ozone will readily oxidize certain contaminants in the water causing system fouling and reduced performance. This being the case, systems used for dental waterline applications require the purchase, storing, cost and physical addition of distilled water to the reservoir every day. Similar to an independent bottle system, the ozone system water reservoir can run out of treated water and require filling of the reservoir along with a prescribed wait "kill time," possibly necessary during a patient procedure. The steep initial purchase price of the ozone system, cost of electricity and water, daily labor procedures as well as the cost of annual filter replacements can make this type of system quite costly and inefficient.

Ultraviolet systems, although not as powerful as ozone systems, can be quite effective at controlling normal planktonic microbial populations. However, they have their own set of problems. An electrical power source must be available. The water used needs to be of high quality since particulate in the water flowing through the U/V chamber can protect an organism from the U/V light and allow it to pass through the system.

Additionally, films, organics, tannins and oxidized contaminants can build-up on the quartz tube in the chamber preventing sufficient U/V light to make contact with the organisms. By its nature, a U/V bulb begins losing its power immediately after installation and must be monitored or replaced on a regular basis in order to maintain sufficient "killing power" within the system. An added concern is that U/V has not been shown to be effective

against certain encysting protozoan forms like *Giardia* and *Cryptosporidium* unless accompanied by sub-micron filtration. Further, U/V offers no residual protection after the system to help prevent re-contamination and has no effect on pre-existing biofilms. Thee is also the cost and time involved to clean the quartz tube and replace the U/V bulb.
The Centers for Disease Control and Prevention (CDC) makes the following conclusion relative to various treatment strategies including independent water supplies, chemical disinfection, draining and air purging regimens, and point-of-use water filters:

"… In fact, preliminary data suggest that none of the proposed methods appear to permanently eradicate biofilms, thus, a combination of these strategies may be necessary to control biofilm formation and thereby improve water quality." (see www.cdc.gov for complete details*)*

How to stop waterline contamination in its tracks.

Vista Research Group, LLC has over 20 years experience in the science and treatment of water and spent years researching possible solutions to the dental waterline problem. As was pointed out by the ADA and others, no one approach seemed adequate for solving the problem. Each method discussed earlier has drawbacks including high initial cost, high annual maintenance costs, labor-intensive daily or weekly maintenance regimens required by staff, and/or frequent filter replacements, etc.

After much research, development, testing, working with practicing dentists, dental technicians, governmental agencies, and a major dental school, we've created several highly effective products that help solve the problem. The ***VistaClear*** **Dental Waterline Treatment System** and ***VistaClean*** **Irrigant Solution Concentrate** have been proven to greatly reduce contamination in dental waterlines. The following information will give you a very detailed look into the multiple technologies used in these proprietary products.

The ***VistaClear*** system is a proprietary system with patents pending that is intended to provide improved water quality and reduce bacterial contamination in dental unit waterlines used for irrigation, cooling, lubrication and scaling procedures. This comprehensive system combines all of the desired methods recommended for control of biofilms in dental waterlines – **filtration**, an off-line **reservoir**, air and water **purging potential** and a simple method for performing occasional **chemical treatment** regimens or adding medicaments.

Figure 9. The Model 1000 ***VistaClear*** is designed to fit in individual operatories and filter all water going to the dental unit for doctor, assistant and hygienist.

Where is the system installed?

There are really two basic systems available to suit your particular needs.

- Model 1000 is designed for an existing operatory and will retrofit into virtually any existing dental unit. The system attaches to the line that supplies your dental control center delivering clean, fresh water to all handpieces, air/water syringes and attached scalers. It can be installed in rear and side delivery cabinets, mounted on a wall or in some junction boxes.

- The Model 1000-C series is designed to be installed in a central location and is best suited to new construction or a remodeling project. The technology is exactly the same as the Model 1000 except it's installed in a centeral location with a dedicated copper line running to each operatory from a central point. It can be located in the sterilization area, equipment room, lab, hallway, basement or any convenient location. All that's in each operatory is a simple valve, ready to provide clean water to your dental unit. Each system is factory-built and comes mounted on a solid white vinyl board ready for installation.

Some key benefits provided by all *VistaClear* systems.

- Provides improved water quality and reduces bacterial contamination in dental unit waterlines used for irrigation, cooling, lubrication and scaling procedures
- NO bottled water to buy, carry or transfer
- NO bottles to fill, clean or maintain
- NO dangerous chemicals, ozone, iodine or other potentially allergic or corrosive agents used
- NO handpiece tubing to cut or alteration of existing dental equipment is required
- NO maintenance or attention required daily or between patients
- Works with new or older dental equipment designs
- Includes two year limited warranty
- Inexpensive filter element change required only once per year
- Initial purchase price a fraction of other systems – low cost per operatory
- Material used in construction meet or exceed FDA and/or ANSI/NSF standards
- Removes up to 98% of water-soluble heavy metals like lead, mercury, copper, arsenic, cadmium, etc.
- Removes > 80% of herbicides, pesticides and organic solvents
- Removes up to 99% of chlorine and chloramines residuals
- Removes >66% of trihalomethanes
- Reduces hard water scaling potential in dental control center and attached dental appliances
- Includes patient information pamphlets addressing DUWL issues and how your new ***VistaClear*** operates to solve the dental waterline problems
- Includes DUWL Treatment System Registry Certificate for framing and display in operatory

How the *VistaClear* system works.

The following is a very detailed description of how the multiple technologies used in ***VistaClear*** systems combine to synergistically provide the best methods to improve the quality of water delivered to the dental unit while reducing bacterial levels and other contaminants.

There are a number of proprietary technologies that have been combined into the ***VistaClear*** patent that make it unique. The control manifold directs the flow of cold domestic water, clean compressed air and filtered water out to the mixing chamber for later delivery to the dental unit. The control manifold also contains the injection port and system pressure gauge.

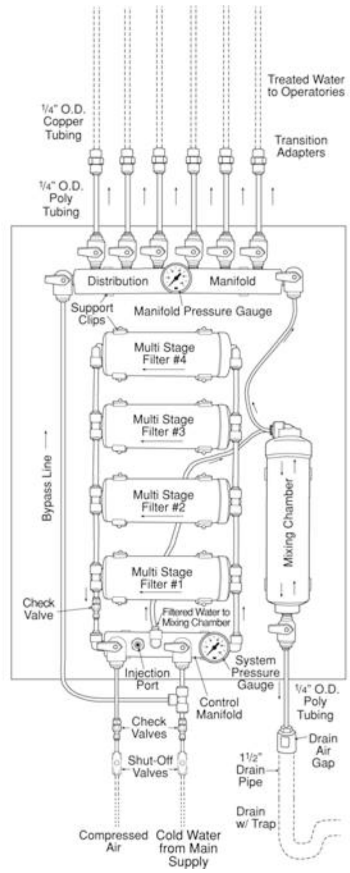

Figure 10. The Model 1000-46-C system shown above is a typical centrally installed ***VistaClear*** designed to filter water for all operatories from one location.

The multi-stage filter element contains a pre-filter pad and large quantity of high-purity redox media. Water constantly flowing past the alloy in the module allows electrons to flow for a very long time and radically affects the *oxidation/reduction* potential (ORP) of the water. In general, different types of microbes can only survive and grow within a particular range of redox potential. One function of the filter design is to force a radical change in the ORP creating an environment that is both bacteriostatic and bactericidal depending on the type of organism.

The water continues past the redox media and travels to the ceramic module where any remaining pathogenic and/or opportunistic, heterotrophic microorganisms, fungi & yeasts or protozoans that may have survived passage through the first portion of the filter are reduced or removed. The multistage filter element contains a proprietary ceramic module design with an absolute rating of 0.90 microns. Although diameter of many microorganisms is smaller than 0.90 microns, a torturous pathway through the ceramic module makes locomotion difficult, if not impossible for most. Therefore, most remaining microbes are superficially retained and die on the surface of the module. Smaller organisms that may enter the pores of the element more deeply are then exposed to elemental silver that has been impregnated into the ceramic during manufacture. This antimicrobial agent helps prolong the life of the filter module.

Figure 11. ***VistaClean*** is a completely natural, non-toxic botanical solution concentrate specially designed to help keep all waterlines clean. As an aqueous cleaner it can be used during patient care or as an aggressive line cleaner if used in higher concentrations. Tests have also shown that ***VistaClean*** does not reduce bond strength.

The final component of the ***VistaClear*** system involves the selective application of chemical agents that may be introduced into the system through the injection port located on the control manifold. Agents (like ***VistaClean*** **Irrigant Solution Concentrate**) may be easily introduced with a standard syringe (less needle) without exposing the system to the contaminated atmosphere. The desired agent is loaded into a luer lock-type syringe (less needle) and injected through the injection port on the control manifold. The water inlet valve is then opened and the introduced concentrate is automatically mixed with fresh, filtered water to create a dilution of the desired agent in the mixing chamber. The agent can then be delivered to the dental unit by either filtered water or compressed air as desired. Complete information about ***VistaClean*** will be discussed later.

A comprehensive approach to protecting dental waterlines against contamination.

As mentioned earlier in this report, microorganisms and resulting biofilms require a methodical approach if one is to be successful in controlling growth. Removing or reducing the organic and inorganic contaminants can be as important as removal of the organisms themselves. The minerals and carbon-containing constituents in the water provide food and structural building components for the biofilm matrix and its residents. ***VistaClear***, with its multiple port manifold, multistage filter, injection port and mixing chamber is able to intercept and deal with multiple contaminants.

VistaClear deals with **pathogenic** and **opportunistic heterotrophs** by creating a zone of strong oxidation/reduction along with ceramic and silver as a first line of defence. All types of **bacteria** along with ***Giardia, Cryptosporidia*** and other protozoans are affected. As a matter of fact, tests have shown 100% removal of live *Giardia lamblia* and *Cryptosporidium parvum* oocysts.

VistaClear and **heavy metals.** Although reduction of heavy metals is not the primary purpose of the system, they are reduced by as much as 98%. The process involves cathodic and anodic activity in the redox media contained in the multi-stage filter element. Water-soluble cations of lead, mercury, copper, nickel, chromium, cadmium, arsenic, antimony, cobalt and most other dissolved heavy metals are removed upon direct contact with the redox medium. The removal process is electrochemical and partially catalytic. For example, soluble lead cations are reduced to insoluble lead atoms and electroplated onto the surface and interstices of the redox medium.

VistaClear remove**s** **chlorine** and **chloramines** in several ways. First, water that contains treatment residuals or chlorine and chloramines passes through the redox media in the multi-stage filter where the residuals are electrochemically reduced to chloride ions. Should any residuals make it past the redox medium, they are reduced by oxidation/reduction in the carbonized resin found in the pores of the ceramic module.

Herbicides, pesticides, industrial solvents, trihalomethanes and other **volatile organic chemicals** are removed or reduced from 66% to over 80%. The mechanism is by absorption onto the carbonized resin found in the pores of ***VistaClear's*** ceramic module.

The redox medium helps prevent the formation and accumulation of **mineral hardness scale**, primarily calcium carbonate. Normal hardness scale from untreated waters is comprised of large, irregularly shaped crystals of calcium and magnesium mineral salts. As water passes through the filter element, certain ions from the redox medium block the formation of carbonate in preference to aragonite. The morphology of the insoluble calcium and magnesium carbonate and sulfate crystals is altered to form relatively small, rounded particles that won't adhere to metallic surfaces and are physically filtered from the water stream.

What is done about films and other contaminants that already exist in waterlines?

Contaminants that exist in the water tubing following the installation point of the ***VistaClear*** must be removed or they will, in fact, re-contaminate the filtered water produced by the system. Whether dental waterlines have only been used for a few weeks or are 15 years old, they will all most certainly have some level of contamination. One of the most unique features of the ***VistaClear*** system is its ability to accept numerous and varied forms of cleaning agents and medicaments. Upon installation it is recommended that ***VistaClean*** **Irrigant Solution Concentrate** be injected into the system and delivered throughout the entire network of waterline tubing that exists in the dental unit. Its safe but powerful cleaning action works to free the internal tubing, handpiece, air/water syringe and ultrasonic scaler lines of preexisting contamination. Again, with total flexibility in mind, the ***VistaClear*** system has been designed to accept virtually any approved or cleared agent for cleaning waterlines.

What is *VistaClean* and how does it work?

VistaClean **Irrigant Solution Concentrate** is an aqueous cleaner derived from natural citrus botanicals designed for use in dental unit waterlines. It may be used in waterlines continuously or intermittently as desired. As an aqueous cleaner, ***VistaClean*** has the ability to safely and effectively remove organic and inorganic contaminants, films, particulates and oxidation products from waterlines and other hard surfaces. It is produced from 100% natural botanicals by a proprietary biotechnical process and contains powerful cleaning characteristics due to the presence of numerous natural components including:

- natural quaternaries
- polyphenols
- limonene
- glycosides
- ascorbic acid and other natural compounds

When used according to directions it is completely non-toxic, safe for the environment, non-corrosive, simple to use and has no negative effect on bonding. It has been tested for safety in both humans and animals, is non-corrosive, considered non-toxic and a non-irritant at dilutions up to 2%. The recommended concentrations are from 0.016% when used continuously to 0.10% or more during line cleaning modes.

VistaClean™
Irrigant Solution Concentrate
by Hu-Friedy

VistaClean **Used With the *VistaClear* Dental Waterline Treatment System**.

As earlier mentioned, ***VistaClean*** is often used as the line cleaner of choice and can be injected into the ***VistaClear*** system by way of the proprietary injection port. It can be used as an irrigant during patient care or as a strong line cleaner depending on the amount used.

Figure 12. When used with ***VistaClear*** filtration system, the ***VistaClean*** concentrate is injected through a proprietary and patent pending injection port with a needle-less syringe which keeps the entire system sealed and protected from outside contamination.

VistaClean **Used With Independent Bottle Systems.**

For those who already own dental delivery equipment with a bottle system, ***VistaClean*** can be used as an irrigant. Many dentists have elected to simply use this method until such time they purchase their ***VistaClear*** system. Each time a bottle is removed for filling, it should be cleaned and filled with fresh water. As was discussed earlier in this report, it is nearly impossible to protect a bulk water supply during storage much less during the loading of water into bottles while in contact with humans in the contaminated atmosphere that exists in a dental setting. To help offset such contamination, ***VistaClean*** can be added to each new bottle used which helps keep the water as clean as possible under such conditions. For example, adding four (4) drops to a 750 ml bottle provides a satisfactory residual level of the aqueous cleaner while keeping it below the taste threshold. Proportionately more can be used with larger bottles depending on the system size.

Bonding tests performed on *VistaClean* at Baylor.

Tests performed at Baylor College of Dentistry in Dallas, Texas, show that ***VistaClean*** has no deleterious effect on dentin bond strength. The purpose of the test was to evaluate the effects of 0.016% ***VistaClean*** on shear bond strength when a flowable composite was bonded to dentin.

Human molars were divided into a treatment and a control group. The dentin surfaces of teeth belonging to the treatment group were exposed to 0.016% ***VistaClean*** while the teeth in the control group were exposed to municipal water. The bonding agent was applied, cured then thermal cycled.

Results of the test revealed that in no case was the bond strength reduced in any of the test specimens. The conclusion drawn was that 0.016% ***VistaClean*** did not adversely affect bonding of a flowable composite to dentin. Recent tests done on other irrigants have shown definite and undesirable reductions in bond strength. The following table shows the summary results of the bond strength testing for ***VistaClean***:

Group Statistics
Dentin Shear Bond Strength – Mega Pascals

Study Group	N	Mean	Std. Deviation	Std. Error Mean
Surface treated with 0.016% *VistaClean*	9	26.315013	7.244398	2.414799
Surface treated with municipal water	10	18.872828	9.876490	3.123220

NOTE: A copy of the entire report is available upon request.

VistaClean can be used quite effectively as an irrigant and aqueous cleaner at various concentrations to help protect dental waterlines without the fear of toxicity or reduction of bond strength.

Why *VistaClear* and *VistaClean* are superior to other products and technologies for improving water quality in dental units.

As was earlier mentioned, the American Dental Association and others have identified the following as potentially viable treatment methodologies for helping clean and maintain dental waterlines:

- Independent water reservoirs
- Chemical treatment regimens
- Daily draining and air purging regimens
- Point-of-use filters

As we previously discussed, *independent bottle reservoir systems* can actually exacerbate the problem of microbial contamination. If, however, you already own such a system and wish to improve the situation, ***VistaClean*** drops can be added each time you fill your bottles for added protection. Compared to other irrigants, ***VistaClean*** is inexpensive, non-toxic, non-corrosive and does not negatively affect bonding.

If the ***VistaClear*** system is used, an independent bottle system is not required since the ***VistaClear*** attaches directly to your existing water supply. No water is manually added and the system is never opened and exposed to contaminated dental environments during operation. Since the system has its own mixing chamber, concentrates of cleaners, medicaments and other agents can be added at will through the proprietary injection port without having to open the system and will automatically be mixed with fresh, filtered water.

Some of the *chemical treatment regimens* suggested by some involve the use of chemical agents that may or may not actually have a effect on biofilm removal but are potentially toxic to humans, corrosive and some are quite expensive. These regimens are prescribed as often as daily but at least weekly which is a burden on staff. As we've discussed, ***VistaClean*** is used as often or as little as necessary and is completely natural, inexpensive, safe for consumption and non-corrosive. And, the use of a ***VistaClear*** system deals directly with the bacterial aspects and other water contamination while drastically minimizing the need for chemical treatment regimens.

The thought of *daily draining and air purging regimens* leaves most dental professionals cold. There are already so many infection control procedures that need done in a dental office today that adding such a time-consuming protocol is more than a burden that likely won't get done daily anyway. Most staff will admit that this protocol is one of the first to be put off when time gets short.

By comparison, when ***VistaClean*** is added to each bottle filled for independent systems, daily purging becomes unnecessary. And when a ***VistaClear*** system is used, most will do a maintenance line cleaning as infrequently as once or twice per month.

Although the *point-of-use filter* can be effective due to the absolute sub-micron rating, it can be extremely time consuming and costly where filter changes are concerned. They often plug, leak and require each treated line to be cut in order to install the filter housing. They have to handle a tremendous biological and physical burden since huge colony counts of organisms build within the dental unit. Besides, they are much like an independent bottle system in that they are opened to the atmosphere each time a filter element is changed.

Conversely, the ***VistaClear*** is usually installed where the full flow of water enters the operatory (for retrofit systems) or at a central point near a main water line (for the central systems). This means that bacteria and other contaminants are dealt with long before they enter the dental unit. The expensive handpiece and air/water syringe lines are not cut with ***VistaClear*** and the entire capital cost of the system is much less than the annual filter element replacement expense for the in-line systems. The proprietary multi-stage filter element on the ***VistaClear*** only needs changed once per year and costs far less than the monthly maintenance cost of the in-line system concept.

When ***VistaClear*** is compared to *ozone and ultraviolet systems* many aspects favoring the ***VistaClear*** become evident. First is capital cost. The typical ozone system costs over twice that of ***VistaClear*** and still requires the addition of distilled water each day and filters each year. Further, ozone residuals are difficult to control and can be quite corrosive to the dental unit and other system components. Ultraviolet systems are costly and must also employ the use of proper filtration to deal with turbidity, organics and other contaminants that can coat the quartz tubes reducing the effective killing output of the system. The ***VistaClear*** is less expensive, does not require electrical power and attacks the biological and chemical contaminants in a completely different way than either of these types of systems.

All *VistaClear* Systems Also Serve As Backflow Prevention Devices.

Discussed earlier in this report was the issue of backflow prevention. The ADA, CDC, AWWA and others all feel that the use of such expensive devices should be commensurate with risk of contamination. In every case the likelihood of contamination of a central water supply system from a dental unit is near zero.

An extra side benefit of the all the central and individual operatory ***VistaClear*** models is the built-in backflow prevention features. ***VistaClear*** systems all employ the use of multiple check valves and other features creating a biomechanical backflow prevention system.

Should negative pressure be applied to the municipal water supply line feeding the system creating a vacuum, water from the patient and dental appliances would be prevented from entering the water system in the following manner:

- The first line of defense is the Mixing Chamber. Water would have to flow backwards into the Chamber, downward through the riser tube, upward through the Air Gap and back into the System Manifold.

- If water were ever able to get past the Mixing Chamber Air Gap and flow back into the System Manifold, it would have to first run through the Multi-Staged Filter in order to get back into the municipal water system. If it did get into the Multi-Stage Filter, the same microbiological and chemical control aspects of the design would deal with bacteria from the patient-side of the filter, remove heavy metals, etc. In other words, the system works just as well in a backward flow situation as it does during forward flow – the water would be microbiologically and chemically "cleaner" than the source water.

- If the water ever made it back through the Multi-Stage Filter and into the System Manifold, several things would happen. If the vacuum were strong enough, the check valve in the Injection Port on the System Manifold would open providing a vacuum break. Further, the water would also have to get past the In-Line Check Valve that is installed on each system. Any vacuum exerted on the system would only serve to strengthen the seal already provided by the stainless steel check in the valve.

- The central ***VistaClear*** systems have additional protection in that there is an individual check valve on the lines running to each operatory and yet another check valve immediately prior to the treated water side of the Control Manifold. These features provide two additional layers of backflow prevention to the municipal system and prevents operatory-to-operatory contamination from occurring.

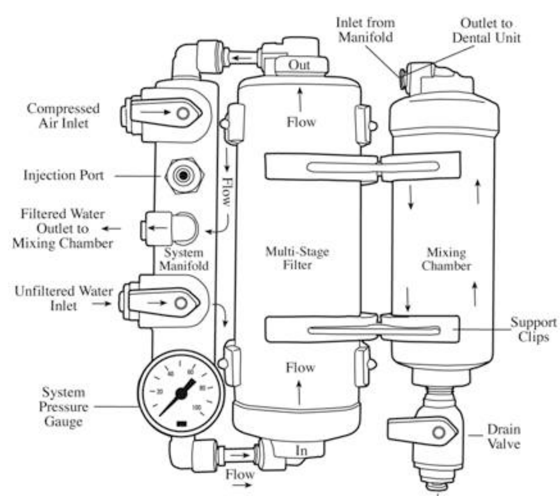

Figure 13. The ***VistaClear*** system also serves as a backflow prevention device by its unique design.

The implications of the built-in backflow prevention features of the ***VistaClear*** system are significant. The ***VistaClear*** systems can address dental waterline contamination problems while using biomechanical means to protect the public water supply against potential backflow. In addition to solving both problems functionally, the capital cost to the dental practice is drastically reduced since the ***VistaClear*** system presents a "two for the price of one" solution – improving water quality while also protecting against backflow and cross contamination.

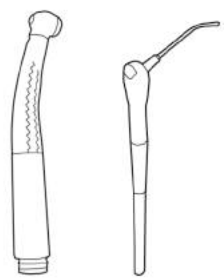

Figure 14. The ***VistaClear*** **Dental Waterline Treatment System** and ***VistaClean*** **Irrigant Solution Concentrate** work to improve the quality of dental waterlines, handpieces, air/water syringes and scalers while also providing backflow protection.

Summary

The problem of biofilms and dental waterline contamination remains a serious issue that must be addressed for the protection of the patient, clinical staff and dentist. The VistaClear dental waterline treatment system and VistaClean irrigant solution concentrate are registered with the FDA as Class 1 medical devices. They have undergone rigorous independent testing at credible dental research facilities. Many products currently available from others have neither been cleared by governmental authorities nor have they been tested as medical devices for use in dental offices.

Where to find *VistaClear* & *VistaClean*.

VistaClear systems are professionally installed by qualified technicians and available for retrofit into existing facilities as well as central systems for remodels or new construction. For information please contact your local dental dealer salesperson or equipment representative anywhere in the USA and Canada.

For technical information or inquiries from outside the USA and Canada, contact ***Vista Research Group, LLC*** at 419-281-3927 or through ***www.vistaclear.com***.

About the author of this Special Report.

Jim Chandler is president of ***Vista Research Group, LLC***, and holds numerous patents with additional patents pending worldwide. Jim has presented hundreds of seminars throughout the USA and Canada over the years on the topics of water contamination and treatment technologies.

Vista Research Group, LLC has nearly 25 years experience in the science and treatment of water and, over the past five years, has been working on ways to solve the problem of dental waterline contamination. After much research, development, testing, working with practicing dentists, dental technicians, governmental agencies, a major dental school, etc., has created a number of highly effective products that help solve the problem and protect patients and the dental staff.

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