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ANTI MICROBIAL APPLICATIONS OF ECA IN DENTISTRY

Scientists exploring infection control problems have been discovering an alarming amount of evidence regarding the safety of the water that is sprayed into the mouth from dental instruments.

A recent study documented in the *Journal of the American Dental Association* concluded that

> "Microbial contamination of dental unit water appears widespread and extensive, and the organisms populating the water lines include many with pathogenic potential which can cause serious illness and death, especially when the immune systems are down."

Among the recent findings: standard microbial culture techniques, as well as new analytical techniques, have revealed extraordinary numbers of a wide variety of waterborne "opportunistic" pathogens. These bacteria are quick to take advantage when the immune system defenses are low, with immuno-compromised patients especially at risk. The bacteria found in dental water lines may cause significant infection in these individuals.

Cystic fibrosis, which occurs in one in 3500 Caucasian births, results in chronic pulmonary disease. Death is most often the result of respiratory failure, typically after many episodes of lung infection. The most common cause of these infections is *pseudomonas*, which are the dominant bacteria found in dental spray water.

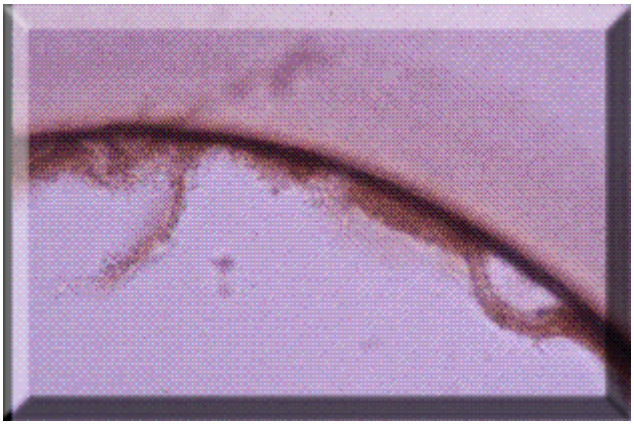
Legionella, the bacteria which cause Legionnaires' disease, are present in dangerously high concentrations in the majority of dental chairs. A prominent California dentist recently died of ***Legionella*****;** the strain of bacteria found in his lungs was present in high concentrations in his office dental water lines.

The Center For Disease Control has implicated ***Legionella*** bacteria as a major complication for people with AIDS. In addition to the well-publicized immune system problems encountered by HIV and AIDS patients, other at-risk elements of the population include individuals with cystic fibrosis, , diabetes, asthma, sickle-cell anemia, those receiving chemotherapy, recreational drug users, transplant patients, heavy antibiotic users and the elderly.

The source of these maverick bacteria which inhabit the dental unit water lines is two fold. First, research indicates that the majority of the organisms originate in the municipal water system. Conventional municipal water treatment procedures are proving inadequate in dealing with a wide variety of these "super bugs".

We need only look at the recent *Cryptosporidium* outbreaks in Milwaukee, Phoenix, Albuquerque, San Antonio, Las Vegas and other municipalities served by state-of-the-art municipal water treatment facilities. Hundreds died in these incidents---hundreds of thousands became acutely ill.

The tiny dental water lines provide a large interior surface area combined with low flow rates and stagnation, two ideal conditions for the formation of a thin slime of microbes called "biofilm" on the interior surfaces of the dental lines.



BIOFILM GROWING IN DENTAL WATERLINE - MAGNIFIED 60X >

This dental water biofilm is an accumulation of dozens of types of microorganisms-stacked and interwoven with each other in a cooperative ecosystem. Layer upon layer of these microbes grow on the inner surface of the dental water line- until occasionally a "clump" breaks free and enters the patient's mouth.

The second source is known as the "suck back" effect, caused by imperfect anti-retraction valves in dental instruments, thus permitting the withdrawal or "suck back" of blood, saliva and other materials from a patient's mouth into the waterline. Research studies have identified a wide range of bacteria resident in the biofilm which originated in patient's mouths

The methodical sterilization of dental instruments between patients providing sterile instruments thus fails to prevent potential pathogens from flowing from the dental water lines through the newly cleaned instrument into the next patient's mouth.

Research studies have clearly shown that efforts to "flush" the water lines between patients are ineffective in removing the biofilm. In fact, flushing leads to incredibly fast re-growth rates due to new organisms and "food" being supplied to the biofilm during the flushing procedure.

Chemical rinses have also proven to be less than effective. Increasing chemical dosages to lethal levels for the biofilm endangers the patient as well as the dental care givers themselves, especially when residues of these chemicals may directly enter the bloodstream during certain invasive procedures.

Concern about the biofilm problem and the potential dangers of bacterial infections originating from municipal water systems has led California to mandate the use of sterile water for all dental surgical procedures.

No mandates exist at this time for general(non-invasive practices). However, the American Dental Association has recommended that dentists investigate the use of technologies which would reduce the total bacteria levels at the output of the dental waterline(patient's mouth) to less than 200 colony forming units(CFU) per milliliter of water. The ADA set this goal for the year 2000.

Considering total CFU measurements in randomly selected dental offices generally reach into the hundreds of thousands, and sometimes 1-3 million CFU/ml, this poses a potentially serious and formidable problem for all professionals involved in general dentistry.

In the "sterile" water conditions identified above(as per California mandate---and soon to be followed by other states), the total CFU count should be held at zero(0) CFU/ml, since bone and soft tissue surgery, including periodontal and endodontics(root canal) work is being done and even a few bacteria can cause post-operative infections or worse.

In this situation, the dentist(oral surgeon) either purchases bulk distilled water or uses a small steam distiller to produce a couple of gallons of steam distilled water each day.

The sterile distilled water is placed in a pressure vessel and then fed into the dental water lines during normal dental procedures. This process is designed to isolate the dental patient, water lines and dental instruments from the municipal water supply, and additional bacterial contamination from that direction.

Unfortunately, the use of sterile water by itself does not ensure a bacteria free dental water line. Studies have shown that even pressurized distilled water sources can be contaminated by suck back effects and other environmental(handling) activities.

The use of the acidic portion of electrolyzed water will solve the 200 CFU/ml general dentistry problem--- by incorporating a combined water purification(distillation) system with a water altering/structuring system which will provide a biocidal capability for all water used in the dental office waterlines leading to the patient. The target of 200 CFU/ml can be met with a "free-standing" water treatment unit(as noted) and without the use of any point-of-use(POU)filtration devices which are designed to remove all bacteria.

For fully sterile water needs(zero CFU/ml) one could solve this additional problem for oral surgery, endodontists, periodontal work, re-constructive surgery, etc. by combining a water purification, structuring and a point-of-use(POU) device such as the FDA-approved Sci-Tech Solutions Clearline Filtration system. Together, these devices will maintain inorganic, organic and microbe-free water throughout the dental water delivery system.

Contamination which may come by way of "suck back" effects will also be contained by the purified/structured water which is entering the system. By maintaining a continual flow of biocidal, structured water in the dental waterlines, it will be easy to maintain the 200 CFU/ml total bacteria count.

As the biocidal water sits in the waterline, biofilm will be killed, layer by layer and it is expected that the residue of this killing process will be sent down the waterline toward the patient's mouth. Adding a device such as the Clearline filter could thus serves at least two key functions:

- it catches the dead bacteria and prevents their migration into the patient's mouth; and
- it catches all live bacteria which may be missed by the biocidal, structured water.

Considering that the 510K FDA approval for the Clearline Filter is for a 5 day use function, by using biocidal, structured water and exposing the Clearline filter to fewer living bacteria, its lifetime can be extended considerably, a fact which will not go unnoticed by the dentist's pocketbook.

The dentist now can attain the 200 CFU/ml target without ripping out his or her entire water system or paying for replacement filters on a daily or weekly basis; the oral surgeon can now have organic, inorganic and microbe-free water in his water delivery system without worrying about suck-back or internal/handling contamination problems which would corrupt that water purity.

The final component to be integrated into this arrangement can come from an existing manufacturer of sterilized, self-contained water containers or bottles(i.e. Adec Inc, et al) which are designed to hold sterilized, distilled water and then repressurize this sterile water into the various dental water lines which traverse the office to the patient.

Many dentists already use independent water bottles, especially those who are involved in various types of invasive procedures. The fact that such devices are already on the market and have the necessary 510(k) approvals can make it easier to integrate the structured/altered water into the system.

Unfortunately, a wide array of articles in the dental trade journals have described the problems which even so-called "sterile" water bottles can encounter. The "one shot" sterilization of the water bottle prior to use does not ensure sterility once water has been added, etc.

In addition, water systems on BRAND NEW dental units can be highly contaminated as shown by Clinical Research Associates(CRA) tests have shown. Up to 30,000 to 50,000 cfu/ml of various bacteria can be found on these brand new systems.

Therefore, it is proposed that a CONTINUOUSLY ACTIVE disinfection system, namely the anti-bacterial, structured water, be used to ensure continuous sterility of the holding container(bottle) while providing this same, biocidal water for use in all dental waterlines attached to this independent water bottle.

In most cases, 510(k) approvals are required only if a piece of dental equipment is "hard wired" into the system. In the present case, the anti-microbial, structured water could be produced by a stand-

alone unit which would be capable of servicing several operatories and associated sterile water bottles. Being physically independent of the existing dental equipments will make it easier for integration into dental operations. Whether or not a 510(k) approval is needed is subject to discussions with the FDA.

NATURE OF THE MARKETPLACE

The dental community has been generally aware of the dental unit water line contamination problem for close to 30 years. In 1993 the American Dental Association(ADA) mobilized a Dental Unit Waterline Task Force incorporating members from the Centers for Disease Control, Food and Drug Administration, US Armed Forces, academia and industry. These professionals have conferred several times since then discussing the results of ongoing scientific studies and possible technological solutions as well as the political and legal ramifications of the issue.

Although higher water standards for dental offices as well as more effective prevention recommendations have always been high on the ADA Task Force agenda, only recently have sketchy guidelines gradually emerged. This emergence has not been one reflecting unanimity within the ADA and even in the face of on-going revelations of additional bacterial contamination problems appearing almost daily in the scientific journals, the ADA continues to send mixed messages to the public and to its 140,000 member dentists.

Meanwhile, the development of products to solve the problem has been slow and has picked up momentum only recently for three reasons:

- the availability of specialized analytical tools for isolating and identifying specific microbes has only recently become available. We hear the words "DNA fingerprinting" on national television quite frequently. Application of that type of technology, combined with other analytical procedures has pushed this contamination issue to the forefront of modern dentistry.
- the increasing number of immunocompromised individuals in the world and their susceptibility to such potentially infections levels of microbial contaminants in dental water.

However, even in this potentially explosive environment, the signals from the ADA continue to be mixed. On one hand, in its Task Force meetings the ADA has made it clear that dispensing water during dental operations that contains more bacteria than untreated sewage must stop and that immunocompromised patients are at special risk.

On the other hand, in a recent landmark case brought by the US Justice Department against a Louisiana dentist for referring AIDS patients, the ADA denied that AIDS patients presented a special risk in dental care.

That brings up the third, and by far the most important reason this issue is taking on acute importance to the dental community:

- **the threat of both individual and class action liability.**

This is precisely why the dental industry is publishing such monthly newsletters as *Dental* Malpractice *Prevention*, which of late have been entirely focused on alerting dentists as to why the contaminated waterline issue could turn into another mass tort litigation as has been seen with DES, Prozac, breast implants, cigarettes and asbestos.

Unfortunately, the number of people exposed to dental unit water and the microbial pathogens reportedly contained there in is enormous, far exceeding the number of cigarette smokers, breast implant patients, persons exposed to asbestos, etc.

Dentists are learning that the risk of such potential litigation with regard to dental waterline contamination is extremely high, since the essential ingredients for such litigation are already present in the here and now:

- a nearly unlimited pool of allegedly "injured" plaintiffs;
- a veritable truckload of scientific literature documenting the potential health risk;
- the availability of cooperative scientists who are willing to define "reasonable scientific probability" broadly to achieve the goals of the litigation;
- emerging government regulation; and
- public awareness raised by popular media reports.

Turn this short list over to a personal injury law firm that doesn't like dentists you will see a lawsuit that makes the current tobacco industry legal disputes look like a Sunday afternoon picnic.

On the positive side of things, dentists are also learning that their liability exposure does not require that the dental unit water be entirely germ free(zero CFU/ml, as in completely sterile water described earlier). Rather they are finding, and now being cautiously told by the ADA, that they seek to employ new protocols in their practice which are designed to limit their patients' exposure to these high levels of microbial contaminants.

In 1996, the ADA recommended(see *Journal* of *the* American *Dental Association*: Issue 127: pp.188) that dentists "give consideration to the use of commercial options for improving water quality". This, and the companion statement in the same issue on pp 185-189) that" by the year 2000, dental unit water used in non-surgical procedures should consistently contain no more than 200 CFU/ml of aerobic heterotrophic mesophilic bacteria at any point in time in the unfiltered output of the dental unit".

Finally, the Office of Sterilization and Asepsis Procedures(OSAP) Research Foundation, in a recent position paper developed by its Dental Unit Waterline Working Group, specifically concurred with the ADA recommendation on control of microbial contamination in dental unit waterlines and attempted to provide a framework for collaboration between industry, scientists and dental practitioners to achieve improvements in the quality of dental water.

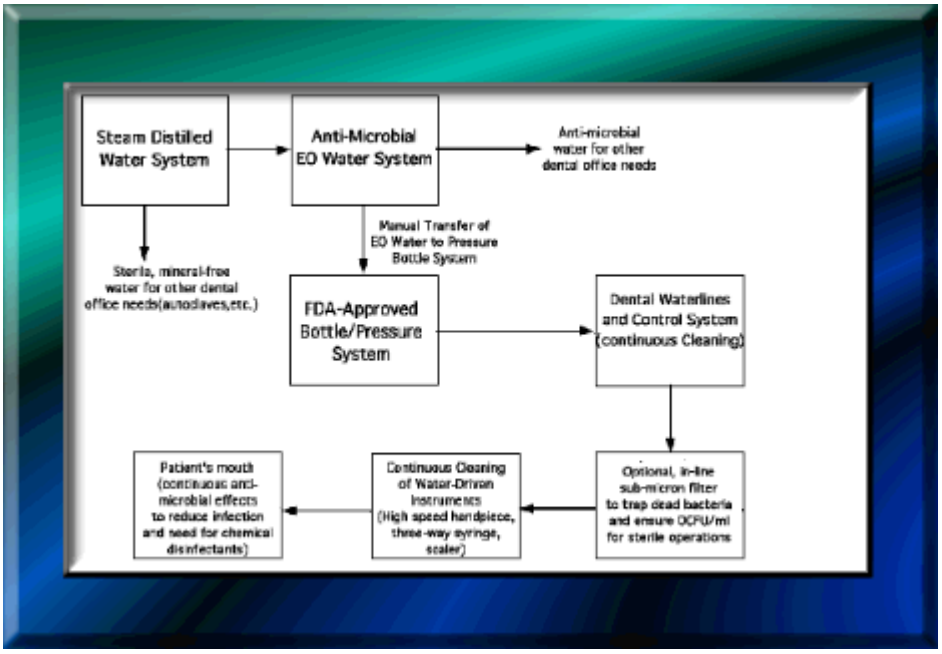
OSAP, in its working paper conclusion stated that:

"When used in a conscientious applied manner, both properly maintained separate water reservoir systems and micro-filtration technology can provide treatment water with 200 or fewer CFU/ml of heterotrophic mesophilic bacteria. A combination of these approaches may offer the best available assurance of high quality dental treatment water quality"

Dental Unit Waterlines Position Paper, OSAP Research Foundation, January, 1997.

IF EVER ONE WANTED A SIGNED AND DATED, >INDUSTRY SANCTIONED PRESCRIPTION >FOR WHAT IS BEING DESCRIBED ABOVE, >THIS IS IT!!

OVERVIEW OF SYSTEM AND OPERATIONAL INTERFACES



Although the structured/altered water technology has potential many applications in the dental area(mouthwash, surface cleaner, instrument cleaner, toothpaste, periodontal and oral surgery sterilant, and others), initial development efforts using electrolyzed water should initially focus on the application of this technology to the dental waterline biofilm problem.

The Anti-microbial Water Production System obtains its "raw" water from an accompanying steam distillation system. The purified water from the accompanying process is processed in batches by the

anti-microbial water production system and manually filled into the on-line, separate water bottle which is then pressurized and feeds the sterilizing water solution into the attached dental waterlines.

As this anti-microbial water passes through the dental waterline, successive layers of biofilm, or individual microbes in suspension in the waterline are exposed to the structured/altered microbial water. *In*- vitro tests conducted on a wide variety of microbes normally found in dental waterlines indicate that these bacteria are destroyed immediately or in a matter of a few seconds.

Water flow through the waterlines is slow and sporadic, thus allowing significant "contact time" between the various microbes and the anti-microbial water.

As this sterilization process continues, dead bacteria will float in suspension toward the dental instrument and eventually to the patient's mouth.

Based on *in-vitro* tests conducted using the anti-microbial water, and considering moderate to heavy concentrations of biofilm and microbes, it is expected that the effectiveness of the anti-microbial water will be such that the system will be able to maintain a CFU/ml concentration less than 200. This would meet the American Dental Association year 2000 goal as stated in the previous section.

If the flow of dead bacteria toward the patient can be tolerated, no in-line, sub-micron filter such as the Sci-Tech Solutions Clearline would be necessary.

On the other hand, if it is desired that these dead bacteria and chunks of biofilm which are periodically released from the interior surfaces of the dental waterline be filtered from the water flow, then the Clearline filter could be inserted to

- trap these dead bacteria; and
- further reduce the CFU count toward what could be considered sterile water (zero CFU/ml).

This represents a typical general dentistry environment where invasive procedures are not in practice. In invasive practices such as periodontal, endodontics and other operations where bone and soft tissue are disturbed, it would be recommended that the Clearline filter be used as general practice.

The water consumption rate per dental operatory chair is only a few quarts per day on the average. A single, centralized anti-microbial water production system could then serve a complete dental facility if its production capacity is sized to a few gallons per day.

Likewise, only a few gallons of "raw" water need be processed by the accompanying distillation system to feed the anti-microbial water processing system.

Normally, a dental office has a dozen other applications for distilled water as well as water which has anti-microbial characteristics. Therefore, one would expect to size both the water distillation system and the anti-microbial water processing system to levels which exceed "on-line" use and which could then provide other services in the dental offices.

Testing which must still be accomplished will be *in-situ* tests using actual dental waterlines and measurements of total bacteria counts before and after the application of the anti-microbial water.

ALTERNATIVES TO ELECTROLYZED, ALTERED WATER

With the increased attention being focused on dental water line contamination, a wide variety of "solutions" have hit the market---some with FDA approval, some without FDA approval. Dentists who are following the lead of the American Dental Association's and OSAP's recommendations listed in the previous section are almost entirely at the risk of promotional claims of the individual manufacturers.

With the exception of removable water bottles which are used to feed sterile, distilled water into the waterlines, there are *no other stand-alone systems which are on the market*

For brevity's sake, all water bottle systems are susceptible to microbial growths and do not ensure that existing biofilm in attached control system and waterlines will not migrate into patient's mouth. Many dentists use separate water bottles to hold sterile water. If such systems could be integrated into the proposed water structuring/altering equipment package, then additional benefits will accrue.

At present, the dental industry is still searching for solutions