Improper Use of Disinfectants in Decontaminating Dental Instruments

Introduction

There is a common belief among many practitioners in the dental community that disinfection is an acceptable alternative to the sterilization of dental instruments. However if these practitioners were to examine established regulations and guidelines that are issued by the US Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), and the American Dental Association (ADA), they would discover that only in limited circumstances is disinfection an acceptable option to sterilization. Unfortunately, this task is not an easy one for the practitioner since these agencies have failed to provide clear uniform language describing when, and when not, to use disinfectants for the decontamination of instruments.

Guidance documents by CDC, FDA, ADA, and other national standards organizations (e.g., ANSI/AAMI) have been written to provide direction to the dental community in achieving proper infection control. Providing documentation for their recommendations with scientific and statistical studies, these agencies provide direction to the dental community on the proper methods to sterilize instruments. But many dental practitioners regard these documents merely as guidelines, having no force of law or enforcement and as a consequence view them as discretionary. In fact, these guidelines have been adopted as "Standard Operating Procedures (SOP's) by many state and local public health regulations and by dental accrediting bodies. Failure by the practitioner to adhere to these adopted SOP's can not only put a patient in jeopardy, but can also lead to an indefensible civil liability.

Disinfectants and Sterilizers are Regulated by FDA as Medical Devices

FDA has been granted the regulatory authority by Congress to establish safety and health criteria for medical devices as codified in 21 CFR Chapter 1, Subchapter H Part 807. Through the 510(k) process FDA grants a manufacturer (or importer) a clearance to market a medical device, establishing conditions under which that device is to be used and to what purpose. Medical and dental instruments are defined within the scope of medical devices.

In 2000 FDA was granted sole authority and jurisdiction to establish criteria for the regulation of liquid sterilants and high level disinfectants as medical devices for the sterilization/high level disinfection of medical and dental instruments (FR Vol. 65, No. 111, pg. 36324; 21 CFR Part 880.6885 and 880.6890).[1] FDA took the position that liquid sterilants and high level disinfectants were an accessory to reusable medical devices and as such, would be defined as medical devices, requiring a 510(k) to market those germicides under the specific conditions of use for specific purpose(s) as defined in 21 Code of Federal Regulations:

"Sec. 880.6885 Liquid chemical sterilants/high level disinfectants.

(a) Identification. A liquid chemical sterilant/high level disinfectant is a germicide

that is intended for use as the terminal step in processing critical and semicritical medical devices prior to patient use. Critical devices make contact with normally sterile tissue or with mucous membranes or body spaces during use. Semicritical devices make contact during use with mucous membranes or nonintact skin."
(b) Classification. Class II (special controls). Guidance on the Content and Format of Premarket Notification (510(k)) Submissions for Liquid Chemical Sterilants/High Level Disinfectants, and user information and training."

"Sec. 880.6890 General purpose disinfectants.
(a) Identification. A general purpose disinfectant is a germicide intended to process noncritical medical devices and equipment surfaces. Noncritical medical devices make only topical contact with intact skin. A general purpose disinfectant can be used to preclean or decontaminate critical or semicritical medical devices prior to terminal sterilization or high level disinfection."

Several points need to be emphasized within the regulations that FDA has adopted:

(1) Liquid chemical sterilants/high-level disinfectants are regulated solely by FDA if they are to be used in the "terminal step in processing critical and semicritical medical devices prior to patient use." A 510(k) clearance is required. FDA provides a listing of current FDA-cleared sterilants and high-level disinfectants.[2]
(2) By regulation FDA defines a critical medical device based on the potential risk for infection associated with its intended use. "Critical devices make contact with normally sterile tissue or with mucous membranes or body spaces during use." FDA has adopted these definitions from CDC.
(3) By regulation, FDA defines a semi-critical device based on potential risk for infection associated with its intended use. "Semicritical devices make contact during use with mucous membranes or nonintact skin." FDA has adopted these definitions from CDC.
(4) By regulation, FDA defines a non-critical devices based on potential risk for infection associated with its intended use. "Noncritical medical devices make only topical contact with intact skin." FDA has adopted these definitions from CDC.
(5) FDA defines a general purpose disinfectant as a germicide intended to process non-critical medical devices and equipment surfaces. A general purpose disinfectant may be used only to pre-clean or decontaminate a critical or semi-critical instrument, but not used as a terminal instrument processing step. General purpose disinfectants are not to be used to disinfect medical or dental instruments.
(6) As a regulated Class II medical device, liquid chemical sterilants/high-level disinfectants must contain label instructions regarding their intended use.

Label Instructions

High level disinfectants and liquid sterilants are required by FDA to have approved instructions for use, including a statement that they are only to be used for heat sensitive semi-critical medical devices. The label must comply with 21 CFR Section

801. Contained within Section 801 are requirements for statements on intended use, including adequate directions to ensure effectiveness as detailed in the sterilant's/ high-level disinfectant's 510(k) clearance. These conditions have been established by treatment efficacy studies documenting the prescribed level of microbial inactivation that is achieved. Failure to follow intended use and instructions for use may jeopardize the effectiveness of the liquid sterilant or the high-level disinfectant.

FDA has taken the position that liquid sterilants and high-level disinfectants are only to be used for heat sensitive medical and dental instruments and which, as a result, require an alternative option for terminal processing. This is indicated by FDA's statement:

> "The FDA regulates the introduction of medical devices into interstate commerce. A person intending to market a liquid chemical sterilant/high- level disinfectant for use on reusable heat sensitive critical and semicritical medical devices must submit a premarket notification [510(k)] submission to the FDA prior to its introduction into interstate commerce."[3]

High-level disinfection represents a lower threshold of microbial efficacy than the threshold established for sterilization. As per CDC:

> "High-level disinfection traditionally is defined as complete elimination of all microorganisms in or on an instrument, except for small numbers of bacterial spores. The FDA definition of high-level disinfection is a sterilant used for a shorter contact time to achieve a 6-log10 kill of an appropriate *Mycobacterium* species."[4]

In contrast traditional thermal sterilization methods (dry and wet heat) must demonstrate a 6-log10 kill (one million-fold spore reduction) of an appropriate thermal-resistant bacterial spore plus it must demonstrate an additional Sterility Assurance Level (SAL) of 10^{-6}, which equates to a demonstrated 12-log10 kill (one trillion-fold spore reduction).

FDA's position to require heat sterilization whenever possible is predicated to the number of variables encountered that may influence the efficacy of the microbial inactivation process when using a liquid sterilant or high-level disinfectant. A list of those variables includes:

(1) The location and concentration microbial contaminants;
(2) Microbial resistance to the sterilant/high-level disinfectant;
(3) Length of time the sterilant/high-level disinfectant has contact with the microorganism;
(4) Concentration of sterilant/high-level disinfectant at time of contact with the microorganism; and
(5) Physical and chemical interferences influencing microbial contact or sterilant/high-level disinfectant concentration.

Although each of these variables must be taken into account in granting FDA clearance for use, situations do arise in which a combination of events or extreme conditions exist which may significantly reduce the treatment efficacy of the sterilant/high-level

disinfectant. Treatment efficacy cannot be verified when using liquid sterilants or high-level disinfectants which further emphasizes the need to follow label instructions for both "Intended Use" and "Directions for Use."

CIDEX® OPA is provided as an example of an FDA-cleared high-level disinfectant. The "Intended Use" statement reads as follows:

> "CIDEX® OPA Solution is a high level disinfectant for reprocessing heat sensitive reusable semi-critical medical devices, for which sterilization is not feasible, and when used according to the "Directions for Use."[5]

FDA makes three points in this statement as prescribed and required under federal regulations:

1. The statement clearly states that "CIDEX® OPA Solution is to be only used on reusable, semi-critical heat sensitive medical devices.;
2. The product is be used only in those circumstances when sterilization is not "feasible"; and
3. The product is only to be used according to FDA prescribed instructions for use.

Defined by FDA, "feasible" means a sterilization device that:

1. Has been validated for use;
2. Is appropriate for dental or healthcare use; and
3. Is readily available for purchase.[6]

For those instruments that are not heat sensitive by either steam sterilization (autoclaving) or by dry heat sterilization, high-level disinfection is not an option or alternative for microbial decontamination.

Further directions are provided on the CIDEX® OPA label under "Directions for Use", "High Level Disinfection" which state the specific conditions under which the product is to be used. As stated for manual instruments processing:

> "Manual Processing: Immerse device completely, filling all lumens and eliminating air pockets, in CIDEX OPA Solution for a minimum of 12 minutes at 20°C (68°F) or higher to destroy all pathogenic microorganisms. Remove device from the solution and rinse thoroughly following the rinsing instructions below."[5]

This instruction precludes the use of wiping as a mechanism for germicidal application or alternative immersion conditions not in accordance with the time and temperatures prescribed.

Use of any disinfectant in any manner not consistent with the instructions on the disinfectant's label is in non-conformance with the FDA clearance granted under the product's 510(k) and violates standards established for the healthcare and dental community that are necessary to provide a safe and effective means to prevent disease transmission.

Importance of Following Disinfectant Label Instructions

Failure to follow label instructions prescribed by the FDA 510(k) can easily lead to disease transmission by not effectively killing pathogenic organisms retained on an instrument from a previous patient or derived environmentally. In too many instances high-level disinfectants as well as general disinfectants are misused in the mistaken belief that any disinfectant is good enough under any form of application.

As noted, general disinfectants can be used on medical and dental instruments only to pre-clean or to decontaminate prior to terminal sterilization or high-level disinfection. General disinfectants (e.g., Cavicide®1) are regulated by the USEPA. As stated on the Cavicide®1 label as an example under Directions for Use: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." Specifically delineated on the label are procedures for (1) "Precleaning Instruments Prior to Disinfection" and for (2) "Disinfecting Precleaned, Non-Critical Medical Devices, Instruments, and Implements." [7,8]

Procedures listed call for complete immersion and soaking of the instruments in the Cavicide®1 solution for up to 5 minutes, depending on the application.[8] There is also a note on the Cavicide®1 label that explicitly states: "Note: Critical and semi-critical devices must be followed by appropriate terminal sterilization/high level disinfection process."[8]

Unfortunately Cavicide®1 is used routinely in dental offices as a disinfectant panacea, wiping instruments as a routine mechanism for terminal disinfection. As noted above, failure to follow these label instructions is a direct violation of federal law.

The misuse of FDA-cleared, high-level disinfectants for terminal processing of instruments appears be commonplace and in many instances, in direct violation of the FDA-cleared label instructions. There are two common areas of misuse: (1) Use of a disinfectant for instruments that are not heat sensitive and (2) Not following prescribed high-level disinfection procedures.

As stated previously, high-level disinfection is viewed by FDA as an option only when no other sterilization alternative is available. There have been some instances where a manufacturer of a medical device provides two decontamination options, high-level disinfection and heat sterilization. This is in total contradiction to the label restrictions for the high-level disinfectant and the dictates of the FDA.

The second non-compliant issue involves the failure to follow the procedures for disinfectant application to the instrument. In too many instances "wiping the instrument down" is viewed by the practitioner as adequate, although in non-compliance with procedures mandating instrument immersion for a specified number of minutes. Wiping is a totally inadequate disinfection procedure, doing very little other than clean the instrument and providing little in the way of microbial kill. Three primary modes of liquid germicide action are required: (1) germicide concentration, (2) microbial contact time, and (3) the ability of the germicide to penetrate into crevices and inaccessible recesses on the instrument. All three modes must be present

to achieve required microbial kill. The wiping mechanism voids both microbial contact time and penetration ability, negating wiping as an effective decontamination mechanism for dental instruments.

To demonstrate how disinfectant efficacy can be adversely affected by solely modifying disinfectant contact time, the following example is offered. In studies conducted by S.E Walsh et al. in evaluating *ortho*-phalaldehyde (OPA), comparisons were made of the killing efficacies of various mycobacteria species.[9] Mycobacteria are highly resistant to both heat and chemical agents and are used as an indicator species to determine disinfectant efficacy.

Various species of mycobacteria are also human pathogens, including the transmission of tuberculosis. There are also non-tuberculosis mycobacteria (NTM) species that are a part of a mycobacterium complex of species including *Mycobacterium chelonae* and *Mycobacterium abscessus* (formerly *M. chelonae var. abscessus*). This NTM mycobacterium complex is responsible for broad spectrum of invasive skin and soft tissue diseases, central nervous system infections, ocular infections, bloodstream infections, and abscesses in both immunocompetent and immunocompromised hosts. *M. chelonae*, and *M. abscessus*, are considered the most drug resistant (multidrug-resistant) of the NTM group with a significant increase of NTM disease transmission documented in the past ten years. Contaminated surgical instruments have been implicated as one source in disease transmission, either as an intermediate patient–to-patient vector or as an environmental contaminant.[10,11]

In the study conducted by S.E. Walsh et al., several species of Mycobacteria were dried at concentrations of 6 to 7 Logs per glass carrier and immersed with 0.5% (w/v) OPA. Mycobacteria exposures to the OPA ranged from 1.0 minute to 30 minutes (only the 1, 2, 5 and 10 minutes exposures are shown in Table I). After each exposure time, resultant Mycobacterium Log reductions were assessed. Results are shown in Table I.

Table I

Contact Time (Min.) 0.5% (w/v) OPA	*M. chelonae var.abscessus* Log Reduction	*M. chelonae* (Epping) Log Reduction[1]	*M. chelonae* (Harefield) Log Reduction[1]	Average Log Reduction
1	3.67	2.28	1.88	2.61
2	4.11	2.65	1.84	2.87
5	3.62	5.32	3.70	4.21
10	5.56	$\geq$ 6	$\geq$ 6	~6

[1] Glutaraldehyde-resistant strain

As demonstrated, a one-minute exposure with complete immersion in 0.5% OPA, resulted in Log reductions that ranged from 1.88 Logs to 3.67 Logs with an average of 2.61 Log reduction. This level of microbial kill does not meet the FDA definition of "Intermediate Level Disinfection", which is defined as "the 6-log reduction of the mixed suspension of vegetative organisms and a 3-log reduction of an appropriate mycobacterium species."

Even at a two-minute exposure, the average Log reduction is 2.87 Logs, a marginal increase in Log reduction from the one-minute exposure and which still does not meet FDA's intermediate level disinfection level threshold. As exposure time progresses to five- and ten-minutes, the average Log reduction increases to 4.21 Logs and ~6 Logs, respectively. CIDEX® OPA label requirements require a 12-minute exposure to assure a 6 Log kill of Mycobacterium that meets the high-level disinfection definitional requirements.

Data demonstrates that high-level disinfectant exposure time is critical in microbial reduction. Two-minute immersion exposure to 0.5% OPA is still not sufficient to achieve an average level of Mycobacterium kill above the lowest germicidal threshold. This level of disinfection is inadequate to provide the conditions necessary to assure disease transmission does not occur.

The data from S.E. Walsh et al. is instrumental in a comparison of the effectiveness of any wiping method in which germicide penetration and exposure times would be minimal, certainly far less than achieved in the one- to two-minute exposures times used in this study. Wiping methods are arbitrary in their application and are not approved by FDA in any application for instrument cleaning, much more instrument disinfection, providing little or no disease transmission protection.

Summary

Disinfectants are commonly misused in the decontamination of dental instruments. FDA regulations and guidance standards have been established to assure that sterilization equipment and liquid high-level disinfectants provide the level of decontamination necessary to prevent disease transmission through improperly decontaminated dental instruments. Failure to follow "Directions for Use" specifically written for sterilization equipment and for high-level disinfectants negates the intent of these regulations and standards that protect the patient from instrument mediated disease transmission. Strict standards mandated by FDA for sterilizer and high-level disinfection manufacturers must be maintained by the dental practitioner who is ultimately responsible for the patient's health and well-being.

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