EDITORIAL Thank You, FDA!



On July 28 of this year, the U.S. Food and Drug Administration (FDA) issued a final regulation that reclassified dental amalgam from a Class I (low risk) to a Class II (moderate risk) medical device, placing it into the same risk classification as dental gold and composite resin filling materials. During a news conference, Dr. Susan Runner, Acting Director for the FDA's Division of Anesthesiology, General Hospital, Infection Control and Dental Devices, indicated that the "best scientific evidence supports the conclusion that patients with dental amalgam fillings are not at risk for mercury-associated adverse health effects. Long-term clinical studies in adults and children aged 6 and older with dental amalgam fillings have not established a causal link between dental amalgam and adverse health effects."

The FDA, however, can impose special controls on the product, as a Class II medical device, to provide a reasonable assurance of safety and efficacy. The FDA specifically recommended that amalgam materials be labeled with the following information:

• A warning against the use of dental amalgam in patients with mercury allergy

• A warning that dental professional use adequate ventilation when handling the material

• A statement of the scientific evidence on the benefits and risks of dental amalgam, including the risks of inhaled mercury vapor.

Call me "old fashioned," an "old timer," "old school," an "old fart," or yes, even a "prosthosaurus," but dental amalgam is *still* the first restorative material I think of for use as a core foundation material, and for restoring interproximal caries in posterior teeth. Having practiced dentistry for 32 years, and academic prosthodontics for 25 years, I have discovered that this material simply works. I cannot tell you how many of our predoctoral dental students have been into other clinical areas of our dental school (UNC-Chapel Hill), placed composite resin or other restorative materials as core foundations, and then shown up in the Prosthodontics clinic to prepare the teeth for full-coverage crown restorations. Some time during the process, they remove the interim restoration only to find the core foundation material retained within the interim restoration. It happened just last week when a thirdyear student removed his provisional to deliver his permanent crown-back to the drawing board. This seems to be a frequent occurrence with "bonded" restorative materials, but it rarely occurs with dental amalgam, at least in our institution. Do not get me wrong-any restorative material will work if properly used, and when fundamental tooth preparation design principles are employed. What I see is so many individuals extolling the virtues of the "bonded composite restoration," while failing to consider that the placement of some undercuts or retention into the tooth preparation may actually enhance the restoration's ability to be retained within the tooth. Or, perhaps they might consider (heaven forbid), that other retentive device called the threaded pin to help retain the material-I am confident that we have some faculty who do not even know how to use a threaded pin for retention. Is this a sign of the times? Perhaps.

We have had the same issue with cast gold restorations, where many dental institutions have stopped teaching its use (particularly the partial veneer gold onlay restoration) in lieu of the more "glamorous" all-ceramic restorations. I will challenge each of you to check in the mirror, in your own mouth—how many gold restorations are there, how many amalgams, and how many composite restorations? I bet I can guess. If it is good enough for you, why is it not good enough for your patients? If it is merely an esthetic issue, I will buy your argument; if it is a safety issue, you might want to read the FDA's ruling here's the link: http://www.fda.gov/NewsEvents/Newsroom/ PressAnnouncements/ucm173992.htm

I have always been a strong advocate of Prosthodontists being the "early adopters" of new dental materials and technologies. That being said, there are still a lot of dental materials available, with proven track records, with excellent longevity, and with years of clinical excellence behind them. Dental amalgam is one of those materials. What is "new" in the marketplace may not necessarily be what is "best" for our patients. If you are not having that discussion about the risks and benefits of *any* restorative dental material with your patient, you should be. My sincerest congratulations to the FDA on this bold statement.

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