

Editorial

Patient protection before personal profit

Why would a dentist use a material containing formaldehyde for root canal treatment as called for in the Sargenti technique? It is inconceivable that the so-called N2 material in use in the USA since 1958, after it was introduced by Angelo Sargenti, a general practitioner from Switzerland, has not undergone greater scrutiny. While anecdotal reports abound, it is equally incredible that the American Endodontic Society (AES), an organization founded in 1968 to teach and motivate dentists to use the Sargenti technique, has apparently not funded, supported, or documented even one published scientific, peer-reviewed clinical study to support the safety of the technique. Anecdotal reports are simply not acceptable where the public health is at stake.

About a year ago, the American Dental Association Council on Dental Therapeutics adopted the following resolution: "Resolved, that, in view of the fact that sufficient data have not been submitted to the Council on Dental Therapeutics to establish the safety of paraformaldehyde-containing root canal filling materials and that the FDA has not approved any products with this formulation, the council cannot recommend the use of these products at this time." In addition, the American Association of Endodontists (AAE), the recognized organization of endodontic specialists, is vehemently opposed to use of the Sargenti technique.

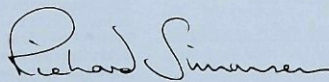
Paraformaldehyde, the solid form of formaldehyde, is an active constituent of N2. Formaldehyde can cause irreversible damage to tissues—particularly susceptible are the tissues near the apex of the root canal. While formaldehyde is an active constituent of other materials infrequently used in dentistry, such as formocresol, it is generally not sealed into the body—at least until the neighborhood mortician gets hold of us—except in the Sargenti technique.

Why is a material like N2 used? It is a material that has been subject to FDA regulatory recalls and destruction of stocks. It is a material that users must have made up by a pharmacy because it cannot be distributed in interstate commerce since it lacks the necessary safety and efficacy approvals. Furthermore, how can dentists justify using a highly controversial procedure that is not taught in any US dental school? Doesn't all this ring some distant alarm bells?

Is it for the benefit of the patient that this unapproved treatment is proposed? Surely not when very adequate alternative materials that are known to be safe are available. Problem is, the alternative materials and techniques take a longer time. The Sargenti technique is used because it is faster to accomplish than conventional treatment. Is the fee charged by Sargenti practitioners fairly and comparatively reduced for the shortened procedure time? Unlikely. Would practitioners using the Sargenti technique continue to use it if it took as long as, or longer than, conventional treatment? I think not. The patient, therefore, is in many cases given an unapproved, potentially dangerous treatment, at the same cost as conventional treatment. The rationalization of the users is that it works, which it does. But it is unacceptable that claims of safety be based, as they are, entirely on unsubstantiated, unscientific anecdotal reports.

While I have heard and read many claims, particularly from AES members, that the Sargenti technique is safe and effective, I have yet to hear anyone talk about the key issue. Is the Sargenti technique better than (not equal to but *better than*) conventional gutta-percha root canal treatment? If it is not better, and if it puts the patient at risk for some of the serious problems related to overfilling, destruction of connective tissues, paresthesia of the mandibular nerve, and intractable pain, and if there are no documented scientific safety and efficacy studies, then why use it? Is it just because it is easier and more profitable? I sincerely hope that a concerned group of general dentists such as the AES is not basing its support for a questionable and unapproved procedure on higher profit. That would be the ultimate rejection of public trust.

Any dentist using the Sargenti technique, despite the unanswered questions of safety, risks being accused of putting personal profit before patient protection.



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