

Angelo G. Sargenti: Madman or Messiah?

An Endodontist

Reveals Myths and Half-Truths Behind the Sargenti Controversy

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Since the Sargenti method of endodontics was introduced to the United States, many general dentist enthusiasts of the method have felt that they could practice more endodontics themselves, thus removing the need for a specialist in many cases. If the enthusiasm of the Sargenti advocates led to overconfidence, the resentment of the specialists led to equally unfounded claims that the Sargenti material is dangerous, leading to a full-fledged turf war that has caused much fear, anxiety, and harmful misperception among the patient population.

I am ashamed of the actions of the American Association of Endodontists (AAE) and its long, organized, and public smear campaign against my general dentist colleagues (including its “position statement,” its “bibliography” on Sargenti, the comments by its members and representatives on television programs and elsewhere, and its (failing) effort to have the FDA ban N2) that has led to patients questioning the safety of any root canal treatment and has damaged the dentist/patient relationship, which must be based on mutual trust. In the interest of restoring this trust and confidence, it is important to examine the myths and realities, the truths and half-truths, of the N2 controversy in the light of true science and reason and in the absence of junk science and demagoguery.

HALF-TRUTH: N2 is toxic.

WHOLE TRUTH: All sealers are toxic,¹ but a basic tenet of toxicology is that “the dose makes the poison.” Indeed, the recognized scientific phenomenon of “hormesis” means that hazardous chemicals at low doses are not just harmless but can even be beneficial. Nutrients like salt and vitamin D are poisons when used in large concentrations, yet they are essential for life. Fluoride is also a potent poison in large concentrations. Coumadin is a well-known blood thinner that many depend upon to live; it is also available in higher concentrations as rat poison.

AAE has sensationally compared N2 to “embalming fluid.”² N2 is 4.5% formaldehyde; embalming fluid is 40%. Formocresol, the pulpotomy agent and intracanal medicament advocated in my endodontic training at the University of Pennsylvania, is 19% formaldehyde. Even Dr. Larz Spangberg, a critic of N2, has stated that the

amount of formaldehyde in a root canal is negligible from a toxicological point of view and that the exposure is “insignificant.”³

MYTH: Gutta percha and the leading sealers are inert.

REALITY: Endodontist Gerald Dietz, Sr.⁴ calls “conventional” endodontic materials “nontoxic.” In fact, gutta percha was shown to be highly toxic by Munaco.⁵ Pascon confirmed that gutta percha is cytotoxic.³ Nonetheless, the falsehood that both gutta percha and Grossman's sealer are “inert” is repeated in the sixth edition of the endodontic textbook *Pathways of the Pulp*.⁶ No matter that the same textbook describes Grossman's sealer as “quite toxic” in the immediately preceding chapter.⁷ Das⁸ found zinc oxide, the main ingredient in Grossman's sealer powder component, to be quite toxic, and Grossman calls eugenol, the liquid component, “irritating.”⁹

MYTH: Other sealers are less toxic than N2.

REALITY: Sam Seltzer and his colleagues at the University of Pennsylvania showed that N2 is less irritating than the Grossman's-type sealer that they tested in dogs.¹⁰ A *Journal of Endodontics* investigation confirms that Grossman's sealer is more toxic than N2.¹¹ There are other studies with conflicting results, but Ingle states the following in the third edition of his textbook: “Summarizing the cytotoxicity studies, one is struck with the sad conclusion that all the products tested are tissue toxic, and that it is only a matter of degree, which is the most, and which is the least. Zinc oxide-eugenol, the longtime standard against which other sealers are tested, comes off poorly.”¹

MYTH: Paraformaldehyde is especially toxic.

REALITY: Formaldehyde is a normal metabolite found in every cell of your body. It is manufactured daily in the liver. After entering the bloodstream, formaldehyde is broken down into carbon and water within 90 seconds. Formaldehyde is ubiquitous in our ecology and is present in the air we breathe.³ Dental composite resins release formaldehyde.¹²

The AAE, in its original position statement, labeled

paraformaldehyde “a potentially dangerous chemical.” The choice of words was interesting as every chemical is potentially dangerous. Formaldehyde is contained in toothpaste, mouthwash, cosmetics, and air fresheners.¹³ It is a common food preservative, and data from the World Health Organization suggest that there is more formaldehyde in a quart of milk than in a tooth obturated with N2.¹³

The current AAE position statement asserts that “Public health concerns and litigation have made the AAE aware of a significant number of patients who have suffered injuries as a result of treatment with filling materials and sealers containing paraformaldehyde.” Oddly, the AAE looks to litigation instead of the scientific literature to stay informed. In reality, litigation involving gutta percha-based endodontics far exceeds that involving N2.

The AAE's position statement continues, “Undoubtedly, there are many other patients who have also suffered injuries because of these materials, but whose injuries have not been publicly disclosed.” Such an unsupported claim is nothing but a smear-scientific McCarthyism.

In a letter to the FDA advocating formal approval of N2, Gordon Christensen, the eminent dental researcher, states that “many other [dental] medications, cements... and other materials have significantly more toxic potential. Even some foods contain agents that are more dangerous...Clinical success is the final research test.”¹⁴ Root canal treatments other than N2 have been shown to have potential adverse side effects including, but not limited to, endodontic failure attendant to bacterial contamination; permanent paresthesia; ankylosis; tissue inflammation; infection; Ludwig's angina; cavernous sinus thrombosis; brain abscess; and death.

MYTH: The active ingredients of N2 have been found to travel throughout the body and have been shown to infiltrate the blood, lymph nodes, adrenal glands, kidney, spleen, liver, and brain.

REALITY: The claim made in the AAE position statement and elsewhere that ingredients of N2 travel systemically throughout the body is specious. First, there has never been a single case report in the scientific literature of any systemic effect attributable to N2. The tiny amounts of this material used in a tooth make such systemic effects scientifically implausible. Studies suggesting that ingredients of N2 travel systemically¹⁵ are junk science. It is disturbing that endodontist peer reviewers would serve as willing rubber stamps for a fallacious toxicology-based finding by accepting its publication into a peer-reviewed endodontic journal—all scientists trust that peer-reviewed material has, in fact, been reviewed by experts in the

field in which the paper is centered. This trust was violated as there could not have been a toxicologist on the panel in this instance.

To explain simply, if you radioactively label an ingredient and then show radioactivity elsewhere in the body, this does not show that the ingredient has traveled through the body¹⁵; it shows only radioactive disintegrates elsewhere in the body. Formaldehyde is rapidly metabolized. In other words, after 90 seconds it is no longer formaldehyde. The fear that root canal sealer components will end up elsewhere in the body is unfounded; it does not happen. Nonetheless, while serving as a defense expert in a multi-plaintiff suit against a dentist and pharmacy, I was confronted by plaintiff's experts who supported the impossible claims of the plaintiff's lawyers. The lawyers had gathered dozens of patients by posting a notice in a workplace, and these patients then agreed that they suffered a long list of truly astonishing systemic effects attributed to N2. The plaintiff's experts in this case were among the most esteemed endodontists in the country and included the author of an endodontic surgery textbook.

HALF-TRUTH: N2 has not been approved by the FDA.

WHOLE TRUTH: No endodontic sealer has ever been approved by the FDA. Nearly all dental materials are classified as devices and not as drugs, despite claims of therapeutic effects or the presence of hazardous material such as mercury. Materials not clearly falling into one category or the other are normally classified as devices.

The manufacturer's claim of therapeutic effect is the only reason that the FDA agreed to look at N2, classifying it as a “new drug” at the request of endodontists, and N2's application for FDA approval will make it the first endodontic sealer ever so approved. N2 is accepted by the European Union and is the treatment of choice throughout much of Europe, Australia, and other developed countries. What kind of root canal treatment do you observe in your patients from other nations?

MYTH: N2 cannot be shipped across state lines because it is dangerous.

REALITY: The popular endodontic textbook *Pathways of the Pulp* goes to the trouble of pointing out the following¹⁷:

The Federal Food, Drug, and Cosmetic Act of 1938 (amended in 1962), prohibits interstate shipment of an unapproved new drug or individual components used to compound the drug ... N-2 may not be shipped interstate or distributed intrastate if any of the N-2 ingredients were acquired interstate. Mail order shipments of N-2 from out-of-state pharmacies in quantities greater

than for single-patient use are considered a bulk sales order rather than a prescription, thus violating FDA regulations.

Indeed, the cases presented by endodontists in lawsuits against general dentists alleging systemic effects of N2 rest primarily on these regulations, along with junk science claims of N2 traveling throughout the body. While obscure regulations and technicalities related to new drugs prohibit interstate sales, any dentist anywhere can use N2 purchased intrastate.

Endodontists have failed to establish that N2 is dangerous and instead trumpet the odd regulatory results of the FDA's misclassification of N2 as a new drug. If the FDA believed that N2 was dangerous, it would remove it from the market. Instead, it has specifically decided not to.

MYTH: Although N2 has been linked to permanent paresthesia, adverse effects of materials used in conventional endodontics are transient.

REALITY: With many millions of N2 treatments the paucity of reported adverse effects is compelling evidence of its safety.

A paper in the *Journal of the American Dental Association* reports paresthesia associated with a “conventional sealant,”¹⁹ currently marketed as ThermaSeal® by Tulsa Dental Products. Joffe²⁰ reports temporary paresthesia and Reeh²¹ reports permanent paresthesia associated with sodium hypochlorite (household bleach). Sodium hypochlorite, the most common endodontic irrigant, has never been approved by the ADA or the FDA for use in the mouth. Indeed, paresthesia can result from an injection alone,²² mere overinstrumentation, or even pulpal necrosis itself.²³

“I have seen cases of permanent paresthesia resulting from calcium hydroxide,” says endodontist William R. Watson, Jr., DDS, MS, FAAOMP of the University of Missouri-Kansas City School of Dentistry²⁴:

Calcium hydroxide is greatly advocated in endodontics, even though it is neurotoxic. It has not invoked the wrath and condemnation of the specialty because as an intracanal medicament, its use does not threaten our specialty. It is always more politically correct to advocate the use or disuse of something in the name of public safety (no matter what the issue) rather than stating the real reason of personal or professional self-interest. Calcium hydroxide, as an intracanal medicament, does not threaten our specialty, so there is no vocal outcry about patient safety.

A 2002 article in the *Journal of Oral and Maxillofacial Surgery*²⁵ serves as a cautionary tale for calcium hydroxide enthusiasts. While calcium hydroxide has long been presumed to be a safe medicament with low

toxicity, calcium hydroxide is, in fact, extremely toxic because of its high pH (12.4) and other properties. The authors report and painstakingly demonstrate that extrusion of calcium hydroxide during endodontic therapy resulted in severe local pain, cyanosis and, necrosis of the face and palate, and trigeminal paresthesia with permanent loss of mandibular nerve function.

Others confirm that calcium hydroxide is cytotoxic and neurotoxic.^{26,27}

MYTH: It is beneath the standard of care to fill the canal with sealer alone.

REALITY: Three different powder and liquid formulations have been certified as safe and effective by the American Dental Association's Council on Dental Materials, Instruments and Equipment when used alone to obturate the canal: Diaket®, Endoseal®, and PCA Root Canal Sealer.¹⁸

MYTH: N2 doesn't work.

REALITY: Endodontist Richard Rajacich writes in *Northwest Dentistry* that Dr. Sargenti is responsible for “an unprecedented period of endodontic failure and retreatment...”²⁸ The AAE agrees, labeling N2 “ineffective” in its position statement.¹⁶ In fact, no study has ever shown that the N2 material or the Sargenti technique is any less successful than any other material or technique.

Gordon Christensen, the foremost dental researcher in the world, has stated, “I do not think that the persecution of the Sargenti technique can continue much longer. Research is too convincing, and the evidence is overwhelming clinically.” Commenting on the outlandish politics that have blocked the method's formal acceptance in the United States, he adds, “It's amazing. [The Sargenti technique] works everywhere else in the world, except America.”²⁹

Several faculty members of my dental school used and advocated N2; these faculty members were in departments other than endodontics. Many approved continuing education courses advocate the use of N2.

The American Dental Association and the Academy of General Dentistry maintain neutral positions on the use of N2. Many foreign dental schools teach the technique as the treatment of choice, and it is perhaps the most popular endodontic technique worldwide.

The use of N2 has long been a political football because when N2 is used, some endodontists fear that the root canal treatment will be quicker, easier, safer, and less costly than that performed by an endodontic specialist. Because this group of specialists has never been able to show that the Sargenti technique is any less successful nor any more dangerous than any other technique in the scientific literature, they first approached

the FDA to classify the sealer as a new drug and then attempted to use the courtroom and the media as part of their public smear campaign.

Millions of teeth have been saved by tens of thousands of dentists using N2 since its introduction in the United States in 1962. A 1990 survey showed that 20% of dentists in the United States have used N2.³⁰ The reports of any adverse effects are much fewer in number than those associated with other materials and are compelling evidence of its safety.

MYTH: Angelo Sargenti would not want N2 in his own mouth.

REALITY: Ingle quotes Dr. Sargenti as saying, “If I had endodontic problems myself...I should certainly ask Dr. Schilder to treat me.”³¹ This statement was lifted out of context. Dr. Sargenti was complimenting Dr. Schilder's technical skill, rather than his choice of cement, after a presentation by Dr. Schilder.

The reality is that Dr. Sargenti indeed had several of his own teeth saved with N2.³² Even if this smear were accurate and Dr. Sargenti did not, in fact, believe in his own technique, this type of gossip is irrelevant and has no place in a textbook that purports to be scientific.

MYTH: Laurie Shoop was badly disfigured by N2.

REALITY: The ABC television show *Prime Time Live* in 1990 presented the sad case of Ms. Laurie Shoop, whose face was said to be “destroyed” by Sargenti. A review of her case suggests that while her face was indeed disfigured, it was not caused by N2, and N2 is simply the ready scapegoat.³³

When Ms. Shoop had symptoms from a previously treated Sargenti root canal (which was not overfilled), the tooth was re-treated by an endodontist. The “conventional” treatment (perhaps not surprisingly) also failed to relieve her symptoms, and Ms. Shoop underwent multiple surgical procedures: apicoectomies, neurectomies, and a partial jaw resection. Her face became disfigured subsequent to the surgeries.

Somewhere along the line, Ms. Shoop's original problem was blamed on the Sargenti material, and she came to believe it, even though she herself had other teeth treated years before with N2 without untoward effect. The AAE worked closely with trial lawyers to arouse the interest of the networks in broadcasting an “anti-Sargenti” segment; the damage to dentist/patient trust may be permanent.

MYTH: The AAE has compiled a bibliography of research that demonstrates that N2 is dangerous.

REALITY: Most of the articles listed in the AAE's

“bibliography” draw conclusions that are in no way supported by the research itself. None of the studies demonstrate that N2 is any less successful, nor any more dangerous, than any other obturating material. In fact, the majority of the articles have already been withdrawn from the ever-shortening list.

The “research” of Larz Spangberg and Kaare Langeland³⁴ is a case in point. Their investigation, for example, begins by stating that the study will determine the “toxicity” of certain materials without ever defining the term or the criteria they will use.

Strangely, while the study purports to investigate 12 different sealers and neither the title, the abstract, the introduction, nor the conclusion mention N2, all of the illustrations relate to the alleged effects of N2. There are no illustrations nor any reporting of the results of the other sealers or of a control when used in the same way. But Spangberg and Langeland don't stop there. They even throw in a so-called “conclusion” in the caption for figure 5. The conclusion is that N2 is not “biologically acceptable.” It is a new and interesting method of scientific writing that lists conclusions in the caption to an illustration. It is even more interesting that while the authors set out to study an undefined concept called “toxicity,” they are now making conclusions about an apparently different concept, the equally undefined “biologic acceptability.” What criteria do the authors employ to determine that a material is not “biologically acceptable?” This question is left unanswered.

In the discussion section, instead of discussing the results of the study, the authors choose to discuss the conclusions of an altogether different investigation. In this other study, which is not available in English, Spangberg injected mercury into the necks of mice. Since the mercury injected in the neck was then distributed throughout the body of the mouse, Spangberg reaches an astonishing conclusion. He states that the experiment shows that material, if compounded into an endodontic sealer, will end up distributed throughout the body of the human.

Listen to this one again: Since injecting a pure component into the neck of a mouse is distributed systemically, then the same systemic distribution is to be expected when a compound is used as a root canal sealer in a human—logic so twisted as to reveal a sinister agenda on the part of the “researchers.” While the methodology is suspect, the “conclusion” has continued to be quoted and referenced for decades as fact.

MYTH: Sargenti endodontics is a sloppy technique.

REALITY: Techniques are not sloppy; operators are. Sargenti, in his textbooks, repeatedly stresses the importance of thorough cleaning and shaping. The currently advocated Sargenti technique is essentially no different

than gutta percha-based endodontics, with the only real difference being the obturating material. A failing case poorly prepared and filled with gutta percha and sealer will succeed when re-treated and filled with N2; a failing case poorly prepared and filled with N2 will succeed when re-treated with gutta percha and sealer.

Sloppy research is hailed by a technique's detractors when the results are pleasing to the detractors' cause; the attitude is that sloppy research is acceptable as long as it is used to cast aspersion upon an out-of-favor technique. Many otherwise superb endodontic textbooks are marred by unsupported statements about N2. We must be ever mindful of the words of Dr. Martin Luther King, Jr.: "Injustice anywhere is a threat to justice everywhere." If it is okay to lie about N2, our own preferred modalities may be victimized next. As for myself, I have never used nor do I advocate the N2 material. I am not a "fan" of any technique; I am just a scientist in search of the truth, who believes in letting the chips fall where they may.

Dr. Sargenti should be recognized for his tremendous contributions. His followers were instrumental in debunking routine culturing and popularizing efficient single-visit treatment³⁵-they introduced mechanical, crown-down instrumentation when such a thing was considered heresy. By questioning our assumptions, Dr. Sargenti reminded us that endodontics is a science, not a religion. Let's accept or reject his proposals, and those of anyone else, on their scientific merit alone.

The AAE will tell you about some of the jury awards in cases where they partner with our trial lawyer "friends." The AAE will not tell you about the defense verdicts in the cases in which they and their plaintiff experts are on the losing side. I recently testified in a case in which the plaintiff, with the help of both an editor of a popular endodontic textbook and the chairman of an endodontic department, sued a dentist for \$2.8 million. The verdict, thankfully, was for the defense.

If any legal concerns are founded in science, let's hear this science. If the legal concerns are not based in science, then we have an obligation as scientists to correct this faulty legal thinking. Why is it that the AAE attempts to establish the danger of N2 in the courtroom? Is it because they are unable to establish it in the scientific literature? The AAE should spend its time and considerable resources advancing treatment and not attacking its providers.

The science and art of endodontics lost a giant when Dr. Angelo Sargenti passed away in 1999. His advocacy of simplified, single-visit, crown-down, mechanized root canal therapy was ahead of its time, and he helped pull the field out of a dark age of irrationality and confusion. His influence will be felt forever because of the love for the field he instilled in countless thousands all around the world.

Dr. Sargenti should be accorded the respect and gratitude he deserves as a pioneer in endodontics. If his advice was imperfect, so it is with all contributors. This specialist thanks him for his effort and contribution and continues the endless search for more perfect treatments and methods.

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References

1. Ingle JJ. Endodontics. 3rd ed. Philadelphia, Pa: Lea & Febiger; 1985:233.
2. Harvard Law School. N2 universal: A case study of a new drug application. Available at: <http://leda.law.harvard.edu/leda/data/64/lbarr.html>. Accessed June 20, 2004.
3. Spangberg LSW. AH26 releases formaldehyde. J Endod. 1993;19:596-598.
4. Dietz G. Two sides of the Sargenti question: Con. J Mich Dental Assoc. 1993;75:37-41.
5. Munaco FS, Miller WA, Everett MM. A study of long-term toxicity of endodontic materials with use of an in vitro model. J Endod. 1978;4:151-157.
6. Cohen S, Burns RC, eds. Pathways of the Pulp. 6th ed. Philadelphia, PA: Mosby; 1994:289.
7. Ibid., p. 265.
8. Das S. Effect of certain dental materials on human pulp in tissue culture. Oral Surg. 1981;52:76-84.
9. Ingle, p. 233.
10. Snyder DE, Seltzer S, Moodnik R. Effects of N2 in experimental endodontic therapy. Oral Surg Oral Med Oral Pathol. 1966;21:635-656.
11. Antrim DD. Evaluation of the cytotoxicity of root canal sealing agents on tissue culture cells in vitro: Grossman's sealer, N2 (permanent), Rickert's sealer, and Cavit. J Endod. 1976;2:111-116.
12. Bardana EJ, Montanaro A. The formaldehyde fiasco: A review of the scientific data. Immunol Allergy Prac. 1987;9:11-24.
13. Formaldehyde. Environmental Health Criteria 89. Geneva, Switzerland: World Health Organization; 1989.
14. Christensen G. Letter. Newsl Am Endod Soc. 1993;71:3-4.

15. Block RM, Lewis RD, Hirsch J, Coffey J, Langeland K. Systemic distribution of ¹⁴C-labeled paraformaldehyde incorporated with formocresol following pulpotomies in dogs. *J Endod.* 1983;9:176-189.
16. American Association of Endodontists. Position statement concerning paraformaldehyde-containing endodontic filling materials and sealers (formerly Position on Sargenti procedure (N2-RC2B) of the American Association of Endodontists). Available at: <http://www.aae.org/dentalpro/guidelines.htm>. Accessed November 12, 2004.
17. Cohen S, Burns RC, eds. *Pathways of the Pulp*. 8th ed. Philadelphia, PA: Mosby; 2002:399.
18. McCann, D. CDT won't recommend Sargenti paste. *ADA News.* 1991;23:1,15-17.
19. Barkhordar RA, Nguyen NT. Paresthesia of the mental nerve after overextension with AH-26 and gutta-percha: Report of case. *J Am Dent Assoc.* 1985;110:202-203.
20. Joffe E. Complication during root canal therapy following accidental extrusion of sodium hypochlorite through the apical foramen. *Gen Dent.* 1991;39:460-461.
21. Reeh ES, Messer HH. Long-term paresthesia following inadvertent forcing of sodium hypochlorite through perforation in incisor. *Endod Dent Traumatol.* 1989;5:200-203.
22. Pogrel MA, Bryan J, Regezi J. Nerve damage associated with inferior alveolar blocks. *JADA.* 1995;126:1150-1155.
23. Antrim DD. Paresthesia of the inferior alveolar nerve caused by periapical pathology. *J Endod.* 1978;4:220-221.
24. Watson WR. Personal communication; 2004.
25. Lindgren P, Eriksson K, Ringberg A. Severe facial ischemia after endodontic treatment. *J Oral Maxillofac Surg.* 2002;60:576-579.
26. Murray PE, Lumley PJ, Ross HF, et al. Tooth slice organ culture for cytotoxicity assessment of dental materials. *Biomaterials.* 2000;21:1711-1721.
27. Brodin, P, Orstavik D. Effects of therapeutic and pulp protecting materials on nerve transmission in vitro. *Scand J Dent Res.* 1983;91:46-50.
28. Rajacich RL. Letter to the Editor. *NW Dentist.* 1999;78:6-4.
29. Christensen G. *Newsl Am Endod Soc.* 1992;70:1-2.
30. Use-survey-1990. *Clin Res Assoc Newsl.* 1990;14:1-3.
31. Ingle, p. 241.
32. Arzt AH. President, N2 Products Corporation (Levittown, PA). Personal communication; 1995.
33. Piacine MJ. 35 years of Sargenti endodontics in America: 1958-1993. American Endodontic Society, Levittown, PA; 1994.
34. Spangberg L, Langeland K. Biologic effects of dental materials: 1. Toxicity of root canal filling materials on HeLa cells in vitro. *Oral Surg.* 1973;35:402-414.
35. Ingle, p. 51.