

This allows the preparation of apparently stable suspensions of either form. However, form I suspensions are metastable at ambient temperatures and eventually will change to form III. The conversion may be hastened by catalytic influences such as strong agitation.

- (1) A. Burger, *Sci. Pharm.* **43**, 161 (1975).
- (2) H. Ueda, N. Nambu, and T. Nagai, *Chem. Pharm. Bull.*, **30**, 2618 (1982).
- (3) J. R. Leary, S. D. Ross, and M. J. K. Thomas, *Pharm. Weekblad. Sci. Ed.*, **3**, 62 (1981).
- (4) D. L. Simmons, R. J. Ranz, N. D. Gyanchandani, and P. Picotte, *Can. J. Pharm. Sci.*, **7**, 121 (1972).
- (5) D. J. W. Grant, M. Mehdizadeh, A. H.-I. Chow, and J. E. Fairbrother, *Int. J. Pharm.*, **18**, 25 (1984).

OPEN FORUM

Safety and Efficacy of Dental Sealants in the Prevention of Tooth Decay

In a recent editorial ("Coming of Age" for Device Technology), Dr. Feldmann¹ appears to be unnecessarily harsh on the use of modern dental sealants in preventing caries. The designation of such procedure as "a hoax or even a well-intended but worthless effort by dentists to protect against the ravages of caries" may have had some validity 15 or so years ago, when the early sealant materials were in developmental stages and application techniques were not well understood. Today, however, new sealants have been developed and clinically proven by dental researchers as safe and effective in preventing caries². The use of sealants by dentists in the United States³ has increased dramatically since 1974 when 37.8% of those surveyed said they offered sealant therapy; in 1982, that figure increased to 57.7%.

The National Dental Caries Prevalence Survey (1979-1980) has shown that among 5- to 17-year-old children, only 16% of the caries incidence occurred in smooth surfaces, but 84% involved chewing surfaces with pits and fissures. It is known that the chewing surfaces of children's teeth are the most susceptible to decay and derive the least benefit from fluorides. The newly developed plastic films are applied to these chewing surfaces to seal the pits and grooves, which prevents food and cariogenic bacteria being trapped and thus offers a new approach to the prevention of dental caries.

The 1983 Consensus Development Conference on the use of dental sealants in the prevention of tooth decay, sponsored by the National Institutes of Health, made the following conclusions⁴:

"The placement of sealants is a highly effective means of preventing pit and fissure caries. It is safe. It is currently underused in both private and public dental health care delivery systems. The reasons for such underuse are complex, but intensive efforts should be taken to increase sealant use. Expanding the use of sealants would substantially reduce the occurrence of dental caries in the population beyond that already achieved by fluorides and other preventive measures. Because dental caries is still a disease common to most young people in the United States and in other countries of the world, such reductions would substantially improve the health of the public and reduce the expenditures for treatment of dental disease. Practitioners, dental health agency directors, and dental educators are urged to incorporate the appropriate use of sealants into their practice and programs."

The American Dental Association Council on Dental Materials, Instruments, and Equipment, which has an acceptance program to evaluate commercially available sealants for safety and efficacy, also considers⁵ "pit and fissure sealants are safe and effective as a caries prevention procedure."

G. Subba Rao
Chief Research Scientist
Division of Biochemistry
Research Institute
American Dental Association
Health Foundation
Chicago, IL 60611

- (6) G. N. Lewis and M. Randall, "Thermodynamics", 2nd ed., McGraw-Hill, New York, N.Y. 1961, p. 227.

Englebert L. Rowe^x
Pharmacy Research
The Upjohn Company
Kalamazoo, MI 49001
Bradley D. Anderson
College of Pharmacy
University of Utah
Salt Lake City, UT 84112

Received January 12, 1984.

Accepted for publication September 20, 1984.

The authors acknowledge the IR analysis and interpretation by Mr. P. Meulman, XRD analysis by Mr. D. S. Aldrich, and assistance on the HPLC assay by Mr. W. F. Beyer, all of The Upjohn Company.

- ¹ E. G. Feldmann, *J. Pharm. Sci.*, **73**, 713 (1984).
- ² "Emphasis: Pit and Fissure Sealant Use, An Issue Explored," *J. Am. Dent. Assoc.*, **108**, 310 (1984).
- ³ "The Role of Health Professional in the Delivery of Caries Prevention," American Dental Association Health Foundation Report, Chicago, Ill., 1983.
- ⁴ "National Institutes of Health Consensus Development Conference Statement on Dental Sealants in the Prevention of Tooth Decay," *J. Am. Dent. Assoc.*, **108**, 233 (1984).
- ⁵ "Pit and Fissure Sealants. Report of Council on Dental Materials, Instruments, and Equipment," *J. Am. Dent. Assoc.*, **107**, 465 (1983).

Author's Response:

Apparently, Dr. Rao misunderstood or misinterpreted the message of my June issue editorial. In his letter, Dr. Rao acknowledges that classifying dental sealants as being worthless 15 or so years ago may have had validity; however, he contends that today they are considered by experts in the field to be a highly beneficial technique in protecting against dental caries.

The entire thrust of the editorial, from its title ("Coming of Age" for Device Technology), through its entire text, to the very last paragraph (which stated that "... what we are witnessing is truly a medical revolution"), emphasized and reemphasized that many modern medical devices, procedures, and technology now constitute valuable health advances—although this was rarely the case a generation ago. As one dramatic example, we mentioned dental sealants and praised the FDA for keeping an open mind in judging positively the current products and their application. Yes, these modern products have indeed been proven to be a safe and effective caries prevention procedure.

Over twenty-five years ago, I personally was on the ADA staff as Director of the American Dental Association's drug testing laboratory. I will remember that the biggest challenge to ADA at that time was to reverse lay, professional, and scientific thinking regarding the value of fluoridation. Until then, only the toxicity and adverse effects were generally recognized and known. But, by carefully adjusting the daily intake of fluoride, remarkable benefits could be achieved while avoiding any adverse reactions. This was one of the earlier technical revolutions in the dental field—sealants are a more recent advance.

In conclusion, we would respectfully urge Dr. Rao to read again our June editorial. Then, it should be clear to him that we have no disagreement whatsoever as to the current value of dental sealants.

Edward G. Feldmann
American Pharmaceutical Association
2215 Constitution Avenue, N.W.
Washington, DC 20037