Mouthrinses
Toothpastes
Alternative
Products

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Over the Counter

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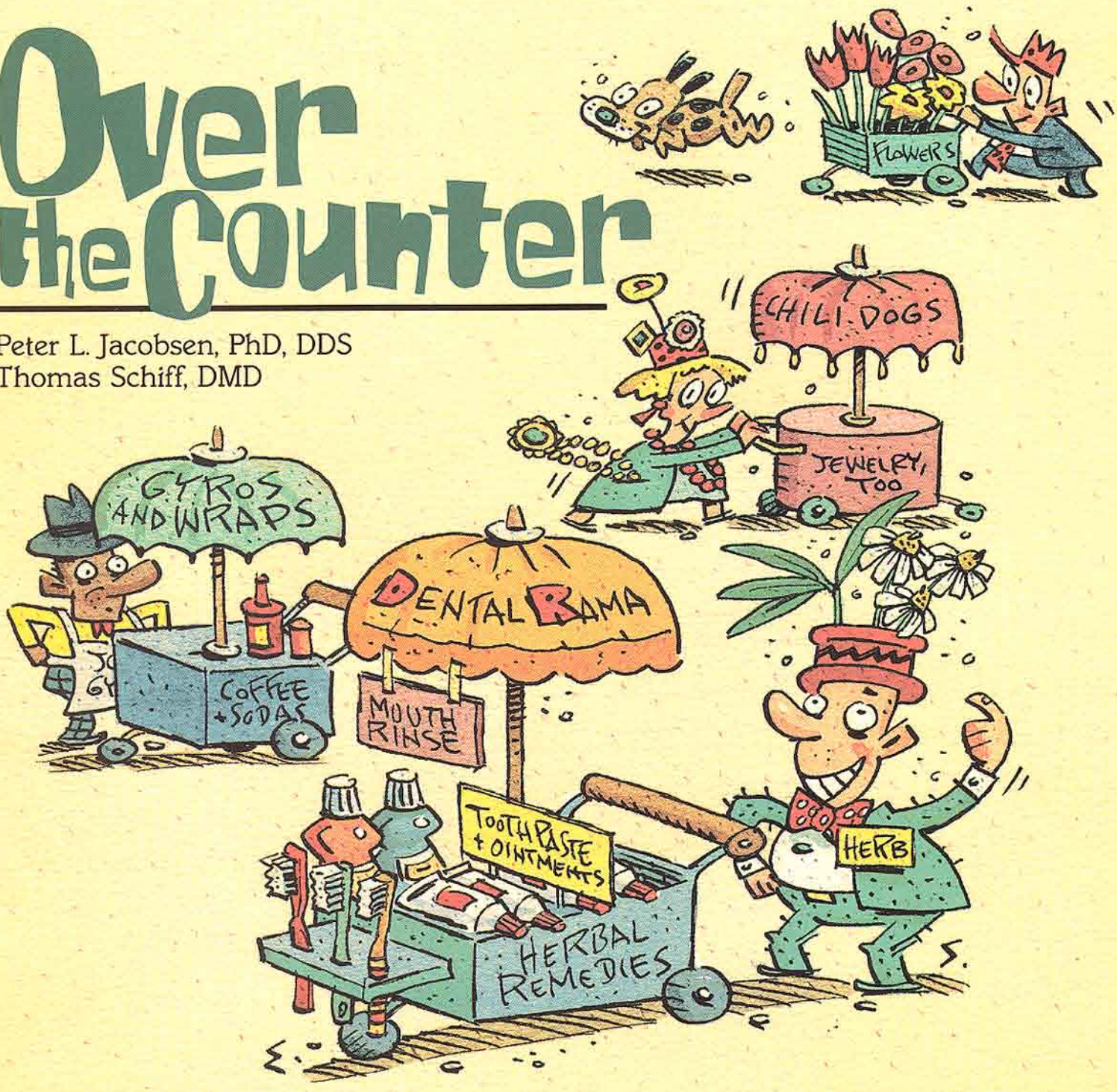

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DEPARTMENTS

FEATURES

CDA JOURNAL, VOL 26, Nº3

Messages of Concern

Jack F. Conley, DDS

On Dec. 16, 1997, Northwestern University announced plans to permanently close its 106-year-old dental school, an institution that has enjoyed a storied place in the history of the dental profession. If the initially announced plan is followed, Northwestern would become the seventh dental school to close in the past 10 years. Upon close examination, the reasons for the closure appear more far reaching and complex than the announcement suggested. We believe there are significant implications to the future of dental education.

What was startling to many observers is that the dental school did not appear to have major weaknesses. The number of applicants was reportedly at an all-time high, the school had $19.9 million in endowments and had a high profile in research, being named one of four oral cancer research centers in the nation by the National Institutes of Health in 1996. The school probably had a mix of strengths and weaknesses not unlike those of any other contemporary dental school. Aside from local, inside factors unknown to those of us outside of Northwestern University that would clearly explain the rationale for the closure, we are led to believe that another, more serious threat to the future of the dental profession itself and to other dental learning centers may help to explain the demise of Northwestern University's dental school.

Education today is a VERY big business. For quite some time, we have been hearing comments from dental school administrators that suggest that dentistry does not enjoy the kind of position of prestige or glamour in the minds of university administrators that the disciplines of medicine, law or engineering occupy. At least a small part of this theory may have been operant in the Northwestern story.

It is not difficult to read between the lines of the public statement of Northwestern administrators in arriving at our conclusion. According to the Northwestern president, "We have taken a careful look at all of our educational programs, and we believe that we should focus our resources on those areas that are central to the mission of the university. ... We intend to have a greater emphasis on research, particularly in medicine and life sciences."A news release also added undergraduate education and "the university's other professional schools" to the greater emphasis list. The troubling message here is that dentistry is not in the same company with medicine and other professional schools. How it can be separated from life sciences is even more difficult to understand.

According to the ADA News, Northwestern's vice president of university relations suggested that "the money required to raise the level of dental education would be better spent elsewhere. Northwestern is a good dental school. But good is not where Northwestern wants to be. We want to be superb." To achieve that would require higher standards and "the cost of achieving those higher standards would be so great as to bring into question whether that is really an appropriate use of the university's resources."

The university provost stated, "Most American universities that have very good medical schools have no dental schools." He went on to suggest that the responsibility for training in the disciplines not included at Northwestern

CDA JOURNAL, VOL 26, Nº3

(soon to include dentistry) "is largely a part of publicly supported universities."

If the philosophy that apparently prevailed relative to dentistry's suitability as a professional discipline at Northwestern University is adopted by other private universities in response to financial circumstances, what will be dentistry's fate? Would a trend questioning the relevance of dentistry as a professional discipline eventually be embraced by public sector higher education as well? For now, we do not believe that such an attitude toward dentistry will develop or prevail. But we do believe the experience at Northwestern sends some tangible messages that all dentists must be sensitive to.

The messages? First, dental school deans and, collectively, the dental profession must do a better job of educating university administrators and boards about the importance of oral health to the American population and about the vital importance of the dental research supplied by our nation's dental schools. If we do not, we will permit administrators to make decisions based upon financial and market share considerations.

In addition, it hasn't been too many years since many dentists were critical of dental education institutions for contributing to an "oversupply of dental manpower." We know that some colleagues are still of the opinion that even their own schools should be educating fewer new dentists, and that there should be fewer schools. The closure of Northwestern would satisfy those holding this belief. If the profession as a whole continues to send the message that it wishes to see fewer dentists educated, and as dental disease is prevented or controlled creating a perception that fewer dental providers and researchers are needed, administrators at American universities could adopt the philosophy apparently applied in the closure of Northwestern and place their resources in support of other disciplines they believe are more important to their image and marketing position.

The messages are clear. We must be more positive and aggressive in ensuring that dentistry continues to receive support as a university educational discipline and is worthy of its status as a profession. To do otherwise will contribute to a much less valued or respected career in the future.

To lose a dental school with the history and reputation of Northwestern is tragic. The implications that this event has for the future of the dental profession are sobering and provide us an opportunity to reflect on the importance of creating a positive relationship between the profession and the educational communities on which it is dependent for its future vitality. As this is written, there is a small possibility that the Northwestern board of trustees could reverse the December announcement. In our view, a reversal would not reduce the importance of the messages that have already been sent to the dental profession.

CDA JOURNAL, VOL 26, Nº3

It's Time to Say 'Thanks for the Assist'

By David G. Jones

They're not unlike the mortar that bonds individual bricks into a wall, or the spokes that make a wheel so strong. They're a legion of almost 60,000 dental assistants across the country, from New York City to San Diego, who are working to help bind together the team of dental professionals who each day seek to improve the oral health of Americans.

Their work is so significant that two decades ago the American Dental Association and American Dental Assistants Association established Dental Assistants Recognition Week. Its purpose is to promote teamwork and recognize dental assistants as an essential part of the dental team. Dental Assistants Recognition Week this year is March 8-14.

"Some dental assistants are fortunate enough to be appreciated on a daily basis, but since they're such a vital part of the dental office, someone once said all dental assistants need to be appreciated, and this is a great way of doing it," says Ruby Roach, CDA, RDA, and president of the California Dental Assistants Association.

Recognizing the importance of dental assistants, CDA annually offers, in conjunction with its subsidiaries, more than $15,000 in scholarships to students who seek to enter the field. The association also has a three-member Auxiliary Recruitment and Retention staff that promotes dental assisting as a career. The ADA and ADAA provide kits to state and local associations to promote activities recognizing dental assistants and sponsor a contest to recognize notable efforts.

"The dental assistant helps the dentist by performing dental treatment procedures they're licensed to do, thereby maximizing both production and profits," says Janet Mitrovich, coordinator of CDA's Council on Education and Professional Relations.

She also said that use of a dental assistant helps improve patient communication.

"Patients are often more willing to ask questions and express concerns to someone other than the dentist," Mitrovich says.

An expert in dental assisting provided another viewpoint honed through more than 40 years of chairside and front office experience.

"There are many duties delegated to RDA's now that in turn allow dentists to do much more diagnostic and other work," says Sally Ingram, CDA, RDA, who began her career in 1954 in the Los Angeles area. "This, and the fact that RDA's are high-quality sorts of individuals, goes a long way in helping to reduce the stress and strain on dentists. Dental fees would also go out of reach of many people if RDA's didn't take more of a role in direct patient care."

Before introduction of the ultra high-speed handpiece in the late 1950s, there was less need for direct patient care, Ingram says, but after its introduction, dental assistants became more important, resulting in "a tremendous evolution in duties."

"We got more involved with direct patient care, and we were excited to be doing it, because we had the opportunity to promote more togetherness in the office because of our ability to do more duties, which helped to integrate us into the team."

Recognizing the increasing importance of the duties dental assistants were performing, the California Board of Dental Examiners in 1976 required testing and registration. Ingram took and passed the first written exam.

"If you're a good worker, you can earn a good salary, and if you're good, you'll always have a job," she says.

Average hourly compensation for dental assistants nationally is $12.60, according to Kristy Borquez, CDA, RDAEF, immediate CDAA past president and ADAA trustee for District 12. Nationally, the highest-paying district, at $15.21, is the 12th, consisting of California, Nevada, Hawaii and Guam. While financial compensation remains a driving force in working as a dental assistant, one dentist, prominent in the profession, explained how good workers in the field can also move up the career ladder.

"In my practice, I have seen three dental assistants take their interest in dentistry to another level," says Eugene Sekiguchi, DDS, CDA's executive director. "Their interest turned to enthusiasm, and I'm proud to say they pursued an educational path to become dentists."

In 1997, 1,985 new dental assistants were registered in California, according to BDE figures. One was Christine Aguilar, who turned her love for children into a dental assisting job at the office of Linda Rafferty, DDS, a Sacramento pediatric dentist.

"I talk to the parents about importance of oral care, and provide some hygiene tips, so by the time I'm done the patient is ready to see the dentist," says Aguilar, a 1997 graduate of Sacramento City College. "It's also a good challenge to help calm down the apprehensive children. I try to make it fun for the kids."

Whether its calming an anxious child, or performing one of a myriad of other challenging duties, dental assistants work to enhance our oral health. And according to Borquez, Dental Assisting Recognition Week provides, "a little recognition that goes a long way toward achieving a winning team which benefits everyone."

CDA JOURNAL, VOL 26, Nº3

Ancient Dental Work Was Ironclad

A 1,900-year old skull from Roman Gaul has yielded surprising evidence of an ancient form of a viable dental implant.

The skull, from a man in his 30s who died in the first or second century, had a fully osseointegrated wrought iron "tooth" where the right second upper premolar should have been, according to an article in the Jan. 1 issue of the journal Nature.

Authors Eric Crubezy and colleagues believe that the original tooth was used as a model for the implant and that the implant was set by impaction soon after the original was lost. The iron's rough surface seems to have provided sufficient adhesion for the bone. It is thought that the implant was placed at least a year before the man's death.

Because of the osseointegration and good positioning, it is believed that the tooth may have been functional.

Denturism Doesn't Take a Bite Out of Prices

In Ontario, denturists have had the right to provide complete dentures to the public since 1974 and partial dentures since 1991. Legislation allowing these changes was passed based on denturists' claims that they could provide these services to patients at a lower charge than dentists could.

A study published in the November 1997 issue of Journal of the Canadian Dental Association, however, finds that no substantial cost savings is being realized.

The study focused on the fee guides published by the Ontario Dental Association and the Denturists Association of Ontario. It did not take into account the differences in training or approach.

The fee guides are published to assist respective members of the associations in setting their own fee schedules. They are also used by third parties and government agencies to establish reimbursement rates for procedures. They represent the maximum a provider would charge for a procedure under normal circumstances.

The study showed that a number of procedure fees were on average 15 percent higher in the ODA fee guide; however, a wide range of prosthetic services were less expensive in the ODA fee guide.

Author Stephen H. Abrams, DDS, says, "An analysis of the fees listed in the 1996 ODA and DAO fee guides revealed no substantial differences between the suggested clinical fees charged by dentists and denturists. In fact, when the cost of laboratory services are factored in, the cost of treatment is higher when the denturist's fee guide is used."

HIV Risk Falls With Postexposure Zidovudine

Postexposure prophylaxis with zidovudine following percutaneous exposure appears to reduce the risk of HIV infection, according to a study published in the Nov. 20, 1997, issue of The New England Journal of Medicine.

The study also found that the risk of HIV infection after percutaneous exposure increases with a larger volume of blood and a higher concentration of HIV in the source blood.

The case-controlled study looked at health care workers with occupational, percutaneous exposure to HIV-infected blood. The case patients were those who seroconverted after exposure, as reported by national survey systems in France, Italy, the United Kingdom and the United States. The controls were health care workers who were exposed but did not seroconvert.

Significant risk factors for seroconversion were found to be deep injury, injury with a device visibly contaminated with blood, procedures involving a needle placed in the source patient's artery or vein, and exposure to blood from a source patient who died of AIDS within two months.

Also, the study indicated that the odds of HIV infection among health care workers who took zidovudine prophylactically after exposure were reduced by 81 percent.

Income Increases for Most Dentists

Three-quarters of dentists in the Pacific region of the United States saw their gross personal income increase in 1996, according to a survey published in the November/December issue of Dental Practice & Finance.

The Pacific region -- consisting of Alaska, California, Hawaii, Oregon and Washington -- lagged behind the rest of the nation in several financial areas according to the survey. At 75.4 percent, the number of dentists whose gross personal income increased was less than the 76.5 percent figure nationally. Also, 70.5 percent of respondents took home more pay (before taxes) than the year before. That figure was 73.2 percent nationally.

Pacific region dentists led the pack in one significant area: cutting overhead. Just more than 24 percent were able to reduce their overhead expenses from the year before while 20.7 percent of dentists nationally were able to accomplish this task.

Other information from the survey:

- One-third of the Pacific region's dentists (32.8 percent) take home less than $100,000.
- Half the region's dentists (50.7 percent) take home from $100,000 to $200,000.
- Of the respondents whose take-home pay increased, most cited working harder and increasing production as the reason.

The information was gathered in a survey of 3,500 dentists, with 1,300 responding overall and 930 providing information on their take-home pay.

CDA JOURNAL, VOL 26, Nº3

Teeth Flee Smokers' Mouths

Smoking increases the risk of tooth loss, and quitting smoking can reduce that risk, according to a study published in the October 1997 issue of the Journal of Dental Research.

The study looked at rates of tooth loss and edentulism of 248 female smokers from the Boston area and 977 male smokers participating in the VA Dental Longitudinal Study in Boston.

The study showed that smokers had increased rates of tooth loss over nonsmokers: 2.4 times for men and 3.5 times for women.

The rates of tooth loss in men were significantly less after they quit smoking but still higher than those of men who never smoked. Although quitting smoking reduces the risk of tooth loss, the authors conclude that it could take decades before the rate declines to that of never smokers.

The study showed no significant differences by smoking history in plaque, tooth mobility, probing depth of less than 2 mm, filled and decayed teeth, and bleeding on probing.

Study Supports Efficacy of Sealants

A study of a sealant program in Australia has shown that the procedure is an excellent way to prevent caries in school children.

The School Dental Service in Victoria places dental sealants on school children. A total of 5,363 sealants placed on 2,875 permanent teeth were examined for retention. Some of the findings on retention rates were as follows after 4 1/2 years:

On premolars, 86 percent were completely retained and 9 percent partially retained.

On maxillary first molars, 63 percent were completely retained, 30 percent partially retained.

On mandibular first molars, 62 percent were complete retained, 32 percent partially retained.

Under partially retained sealants, the caries rate was 4.5 percent. Under completely retained sealants, the caries rate was 0.4 percent. The authors conclude that the School Dental Service sealant program is a sound preventive dental public health approach.

Honors

Dr. Arthur A. Dugoni, dean of the University of the Pacific School of Dentistry, has been selected as the 1997 recipient of the Dr. Irving E. Graber Award, which recognized excellence in the advancement of dental education.

Dr. Gregory P. Johnson of Irvine has been elected president of the California Association of Orthodontists.

CDA JOURNAL, VOL 26, Nº3

Over-the-Counter Dental Products

By Peter L. Jacobsen, PhD, DDS, and Thomas Schiff, DMD

Over-the-counter dental products have captured the hearts, minds and mouths of the American public. The products and the advertising and research that goes into them shape the way the American public perceives oral health. In many ways, product advertising creates dental needs, then proceeds to fill them.

For most of this century, the profession of dentistry was the only scientific and professional resource for the American public. Commercial products fell in the "buyer beware" category. That all changed in 1960 when Procter & Gamble submitted studies on Crest toothpaste with fluoride to the American Dental Association. It received the ADA Seal of Approval for its efficacy in fighting dental decay.

Since that time, industry has led the way in scientific research on a vast array of over-the-counter dental products. The research has developed a range of efficacious products to treat a number of oral problems and diseases. Products are available to manage dental hypersensitivity, dental decay, tarter buildup, teeth staining, halitosis, dry mouth and a variety of other oral needs and desires. Most recently, Colgate has introduced a toothpaste containing Triclosan, which received the ADA Seal of Acceptance for its antigingivitis effect.

Patients turn to the dental professional for information about their oral health and the products available to treat various oral health needs and desires. This issue of the *Journal of the California Dental Association* contains a variety of articles relevant to the over-the-counter dental product market. Some articles will provide specific recommendations to treat specific diseases. Others provide an education about efficacious ingredients that may be available in a broad range of products.

We hope the information in these articles proves to be useful, and we thank the authors for sharing their expertise with the readers of the *CDA Journal*.

CDA JOURNAL, VOL 26, Nº3

The New Toothpastes

By Irwin D. Mandel, DDS

ABSTRACT Fluoride toothpastes that fight cavities have become common. The current competition among products is for the additional benefits they can offer -- with anti-tartar and whitening leading the way. Toothpastes serving special populations have been increasing and now include desensitizing dentifrices, natural toothpastes, smokers toothpastes, and one designed for people with xerostomia. The newest toothpastes are multibenefit products that include among their properties a clinically demonstrated anti-gingivitis effect -- such as Crest Gum Care and Colgate Total, which was recently cleared by the Food and Drug Administration for antiplaque/antigingivitis as well as anticaries effects.

AUTHOR

Irwin D. Mandel, DDS, is a professor emeritus and was formerly asociate dean for research at the Columbia University School of Dental and Oral Surgery.

Historical Background

White teeth have been popular attributes of beauty in many societies since ancient times. In the Bible, when Jacob blessed his children, he promised Judah teeth whiter than milk. According to Cicero, white teeth are the first requirement of beauty. Literature is replete with allusions to teeth comparable to shining pearls. When nature did not live up to expectations, help was elicited from chew sticks and fiber sticks as natural toothbrushes and from a wide range of dentifrice ingredients including ground animal bones (often burned to produce charcoal), egg shells, pumice or chalk as abrasives admixed with honey, salt, myrrh, cinnamon and/or oils.[1]

In colonial America, dentists mixed their own powders and pastes, often advertising them in local newspapers. Their "special" properties made the mixes practice builders and profit centers.[2] Dental powders and creams became increasingly popular when the toothbrush was re-invented by William Addis about 1770 in England and spread to the United States after the Revolutionary War. The toothbrush was originally invented in China hundreds of years before, but technology diffusion was slow and re-invention frequent. Dentifrices were originally sold in ceramic jars into which all family members dipped their damp toothbrushes. The more fastidious people, who undoubtedly were equally appalled by familial toothbrushes, were not accommodated until 1892 when

CDA JOURNAL, VOL 26, Nº3

Dr. Washington Wentworth Sheffield, a dentist in New London, Conn., invented the toothpaste tube. The collapsible metal tube allowed individual portions for each member of a family.[3]

During the 19th century, imported English dentifrices were superseded by vigorously marketed American brands. Psychological advertising evoked fear and embarrassment and lauded the simple solutions provided by products that saved teeth and left them "as white as driven snow and filled the breath with odors of springtide."[2] Not mentioned in these exaggerated claims was the fact that some products were harmful to teeth, containing acids as tooth whiteners and highly abrasive agents as polishers. Beginning in 1909, Professor William J. Gies at Columbia University began an extensive research program relating the composition of various products to their advertising claims. During a 10-year period, he exposed the fake claims and their dangers. Support for American Dental Association action grew, and in 1928 the ADA's Bureau of Chemistry, modeled after the American Medical Association's program, was established. In 1930, the Council on Dental Therapeutics came into being and soon launched a formal acceptance program for dental drug products. The first fluoride dentifrice was accepted in 1960.[2]

The Current Scene

Dentifrices accepted by the ADA Seal Program are in three general categories – desensitizing, fluoride and fluoride with tartar control. A variety of other products, such as various whitening products, are being sold but have not applied for nor been granted the ADA Seal. The procedure for seeking approval of whitening products is described in a supplement to the Journal of The American Dental Association, April 1, 1997. Most dentifrices have similar basic ingredients:

- Abrasives (20 percent to 50 percent);
- Humectants to prevent water loss (20 percent to 40 percent);
- Water (20 percent to 35 percent);
- Binders to stabilize and prevent separation (1 percent to 2 percent);
- Detergents (1 percent to 3 percent); and
- Flavors, sweeteners and preservatives (1 percent to 3 percent).[4]

The therapeutic components are the various fluorides; antitartar compounds; and desensitizing, antibacterial and whitening agents. Dentifrices are available as pastes, gels and liquids in tubes or pumps.

Since the mid 1950s, much of the competition among toothpastes has involved which kind of fluoride is most effective. Fluoride was the first of the therapeutic additions to the basic dentifrice formulations. Stannous fluoride, sodium monofluorophosphate, sodium fluoride and amine fluoride (sold outside the United States) all have their partisans, but the clinical efficacies of properly formulated products are comparable. Advertising and taste rather than therapeutic superiority determine the market advantage. During the past decade, however, it has not been enough for a dentifrice to prevent tooth decay or create a smile that will win the man, woman or job of one's dreams. Now, it seems, a dentifrice must fight tartar, plaque and gum disease as well. And manufacturers do not want to forget "niche" consumers – smokers, natural product fans, people with tooth sensitivity, and those with dry mouths. Increasingly intrusive has been a growing demand not just for stain removal and tooth brightening but for actual whitening of the inherent tooth color.

Anti-Tartar Products

One of the first products to venture beyond fluoride was tartar control toothpaste. The major anti-calculus strategy developed by researchers in the 1970s was to inhibit crystal growth, thus preventing the mineralization of developing plaque and the transition of the plaque into calculus. The most effective agents in vitro were the pyrophosphates, but in the oral cavity these were rapidly broken down by bacterial and salivary pyrophosphatase enzymes. In the 1980s, formulations were created using high concentrations of pyrophosphates (and other polyphosphate salts) that could be combined with sodium fluoride to both reduce tartar buildup (not preformed tartar) and retain anti-caries potency. Indeed, the concentration of sodium fluoride was high enough to serve as an anti-enzyme and help inhibit the limiting pyrophosphatases in the mouth.[5] The addition of 1 percent of a copolymer of methoxy-ethylene and maleic acid (Gantrez, GAF Corp.) appears to improve the effectiveness of some anti-tartar products.[6] The tartar control products that have received the ADA Seal have been shown in appropriately designed clinical studies to be effective decay preventives as well as to significantly reduce the formation of tartar above the gum line. A caveat is included on the label that such products have not been shown to have a therapeutic effect on periodontal disease. The anti-tartar ingredients are considered by both the ADA and FDA to be primarily cosmetic, not therapeutic. They do not affect the already hardened deposits.

Other anti-tartar formulations have not applied for nor received the ADA Seal. One such product, a toothpaste containing Citroxain – a mixture of the enzyme papain, sodium citrate and alumina – has some supporting

CDA JOURNAL, VOL 26, Nº3

published data and is marketed primarily as a whitening toothpaste.[5] Additional anti-tartar products with supporting clinical efficacy data are available in other countries but have not been introduced in the United States. These include 0.5 percent zinc citrate combined with 0.2 percent triclosan -- an effective anti-bacterial agent;[5] triclosan and the polymer Gantrez;7 and pyrophosphate and triclosan.8 The triclosan/Gantrez combination is part of a multibenefit product that has been approved by the ADA and FDA and is awaiting marketing in the United States.

Whitening Toothpastes

Virtually all toothpastes can claim stain removal and tooth brightening. Stain removal in varying degrees is a given in any dentifrice containing an abrasive and detergent and by using a properly directed toothbrush with sufficient contact time. When these elements are augmented by anti-tartar ingredients to reduce pellicle and plaque mineralization and fixation, stain removal can be enhanced. When surface stains are removed, teeth are indeed brighter and appear lighter. Tooth whitening, however, requires modifying the intrinsic tooth color, necessitating chemical alteration of the chromophores within the tooth. This process requires penetration and alteration of tooth substance. Bicarbonate, alumina and polyphosphates cannot whiten teeth; at best they can contribute to stain removal. Whitening requires bleaching or enzymatic disruption. Fortunately, the use of acid penetration and dissolution has not been an acceptable method of whitening for nearly a century.

Numerous dentifrices are now marketed with whitening claims based on the presence of various peroxides – hydrogen, calcium or carbamide. For over-the-counter safety standards, the peroxide content should be kept low and can supply some effervescence and perhaps some very short-lived bleaching. Peroxide is rapidly broken down by oral enzymes from bacteria and saliva. Gel preparations provide longer contact time, but unless used with a tray they are usually ineffective and can be irritating. Safety is very much a concern and effective bleaching is best accomplished through an office procedure or a dentist-prescribed and approved gel formulation in an individually fabricated tray. No whitening toothpaste or over-the-counter gel has applied for or received ADA acceptance for a whitening claim. Such acceptance would require the product to meet the same safety and efficacy standards as the professional gels.

Niche Products

In addition to the basic fluoride-containing, anti-tartar and whitening dentifrices, an increasing number of niche products directed to special segments of the consumer market have been developed in recent years.

Desensitizing Dentifrices

One of the earliest of the special products was directed to people with tooth sensitivity at the gingival margin and exposed root surfaces – an expanding segment of an aging population retaining their teeth for longer periods. Although the number of brands of desensitizing toothpastes and gels has been increasing, the basic desensitizing ingredients have remained the same – strontium chloride, potassium nitrate and sodium citrate in a surfactant gel.[4] The latter two are compatible with fluoride – not so strontium chloride – and ADA accepted fluoride-containing products have to have demonstrated anti-caries ability as well as desensitizing efficacy. Lately, bicarbonate has been incorporated in some products for people with a preference for this ingredient, and most recently one desensitizing toothpaste has added a tartar-control component. These combinations are meant to encourage longer use of the desensitizing paste since they also provide the benefits of regular toothpastes.

Natural Toothpastes

An increasing number of people are attracted to products that do not contain dyes or artificial preservatives or sweeteners, such as saccharine; and natural toothpastes are the beneficiaries of that trend. Part of the appeal of baking soda-containing products are their characterizations as natural. The most popular toothpastes in this category are produced by Tom's of Maine, a pioneer in this area. The company's nonfluoride toothpastes contain propolis – a resin found in beehives that has anti-bacterial properties – and myrrh, for gingival stimulation and astringency, according to the company. The natural toothpaste with fluoride (sodium monofluorophosphate) uses essential oils for flavor and finely ground calcium as an abrasive. It has met the requirements for the ADA Seal and has received FDA clearance.

Several herbal and herbal/bicarbonate toothpastes have been in use in Europe for a number of years. The products contain a variety of plant extracts such as echinacea, sage, camomile, myrrh and rhatany. These ingredients are claimed to have antibacterial and/or anti-inflammatory properties. There are a number of published studies on these products indicating mixed results.[9,10] Similar kinds of products are available in some health food stores in this country

CDA JOURNAL, VOL 26, Nº3

but are not marketed nationally. The sanguinarine-containing toothpaste Viadent also uses an herbal extract but is not marketed as a natural product.

Smokers Toothpastes

Best known in the category of smokers toothpastes is Topol, which depends on a more abrasive form of silica to physically remove the heavy stains resulting from tar and resin deposits. Even such a narrowly focused product is now formulated with fluoride and has met the requirements for the ADA Seal for its gel and toothpaste. However, people with gingival recession and the resulting root exposure should exercise caution with such products because of potential damage to cementum and dentin.

Xerostomia Products

One company, Biotene, has formulated a line of products for oral care aimed at people with dry mouth due to side effects of medication, salivary gland disease (especially Sjogren's syndrome), or head and neck radiation. The products are formulated with bland flavors to be nonirritating to taste buds and soft tissues that can be hypersensitive when chronically dry. The toothpaste (and mouthwash) is theoretically designed to provide some of the natural antibacterial factors present in normal saliva that would be in short supply with deficient salivary function – lysozyme, lactoferrin and peroxidase. Although the approach is conceptually an attractive one, there is no published data to support any significant protective claim.

Multibenefit Products

In a highly competitive dentifrice marketplace with annual sales of more than $1.3 billion, the quest for multibenefit products has been a long and rigorous one. With public recognition of the centrality of supragingival plaque in caries and gingivitis – a recognition strongly enhanced by television advertising – fighting plaque joined stain removal as one of the stated goals of tooth brushing. Antiplaque claims that often went beyond superior cleaning properties to specific attributes of antibacterial ingredients became commonplace. After a period of contention, the ADA took the position for its acceptance program that plaque reduction per se is not a health benefit, and it has to be accompanied by a clinically demonstrated health benefit to merit the ADA Seal. Gingivitis was the most pragmatic goal and plaque/gingivitis became the basis for a new set of guidelines. Up to now these guidelines have only been met by mouthrinses – chlorhexidine and essential oils. The Food and Drug Administration has been moving in a similar direction for oral care products via its advisory panels.

Antiplaque/Antigingivitis

Until very recently, toothpaste products, responding to the ADA position, refrained from making direct antiplaque/antigingivitis claims based on plaque reduction or modification and settled for "fighting plaque and gum disease," or numerous variations thereof. Although overt claims were not made, the presence of particular ingredients such as sanguinarine, baking soda, hydrogen peroxide and baking soda-hydrogen peroxide combinations were projected as being of particular value. Published data does not support an antiplaque/antigingivitis claim for these products.[11,12]

Crest Gum Care

A new product – actually a modernization of the original Crest fluoride toothpaste that is essentially a stabilized stannous fluoride now called Crest Gum Care – has been marketed as an anti-gingivitis product that would be additive to the established anticaries protection of stannous fluoride.[13] This product appears to have overcome some of the stability problems of the original formulation and maintains a stannous fluoride level capable of significantly reducing gingivitis. It does not achieve this added benefit by reducing the amount of plaque per se, but does affect bacterial flora and metabolic processes sufficiently – as measured by plaque glycolysis – to result in an impact on gingivitis.[13] The reductions in a number of studies are in the 10 percent to 20 percent range with a greater reduction in gingival bleeding scores. The results are both statistically and clinically significant, as concluded recently by the Dental Products Panel, an advisory committee to the FDA. The product awaits clearance by the FDA. The new Crest stannous fluoride still retains a drawback of the original: It causes staining in some people. It does not have the ADA Seal.

Crest Multi-Care

Although marketed as a multibenefit product, Crest Multi-Care is essentially an anticaries/antitartar combination. It does not include a specific antigingivitis component and makes no claim other than "protects against mouth acids" – a claim based on in vivo plaque pH measurements. Despite its name, it offers no therapeutic benefits beyond those of other fluoride/antitartar products. It does not carry the ADA Seal.

Colgate Total

The most ambitious of the multibenefit toothpastes to date, Colgate Total has received the ADA Seal and recently cleared the FDA's regulatory

hurdles to become the first toothpaste to be approved for its ability to help prevent plaque, gingivitis and caries. Previously on sale in more than 100 countries, according to the company, Colgate Total reached U.S. consumers early this year.

Total is essentially a sodium fluoride dentifrice containing the broad-spectrum antibacterial agent triclosan (0.3 percent) and the copolymer PVM/MA (polyvinyl methyl ether malic acid), also marketed under the trade name Gantrez (2 percent). Triclosan has been used in soaps and deodorants for more than 20 years. Its broad spectrum of activity encompasses a large range of oral bacteria, and it is compatible with other ingredients in oral products. The combination of triclosan and PVM/MA inhibits crystal growth and is effective as an antitartar agent. A series of four three- and six-month clinical studies supports its value in reducing tartar formation in the range of 23 percent to 55 percent.[7] The antiplaque/antigingivitis efficacy was established in 12 studies of six to seven months in duration, with plaque efficacy vs. placebo from 7 percent to 59 percent and gingivitis efficacy from 19 percent to 32 percent.[7] Some recent studies strongly suggest that part of the triclosan effect on gingivitis is due to anti-inflammatory as well as antibacterial properties.[14]

Conclusion

Undoubtedly, additional multibenefit toothpastes currently marketed outside of the United States will become available here as well. The battle of comparative studies and advertising claims is sure to follow. It's comforting to know that although snow white teeth have been adopted as a national symbol for a dentally conscious public, oral therapeutics is not being neglected. It's not only alive and well, but thriving.

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CDA JOURNAL, VOL 26, Nº3

Alternative Dental Products

By Peter L. Jacobsen, PhD, DDS, and Richard P. Cohan, AB, DDS, MS, MA

ABSTRACT Alternative, complementary or holistic health care is a growing area of medicine and dentistry. There are a variety of dental products promoted as an "alternative" to the standard commercial dental products that most dentists recommend and most patients use. These alternative products can be categorized as standard dental product made with natural ingredients, herbal products, homeopathic products, and synthetic alternative products. The use of dental care products should be based upon sound basic science and sufficient evidence of safety and efficacy. Dental health care providers should be aware of the range of alternative dental products and be able to help their patients understand the type of support/evidence needed to determine safety and efficacy of treatment.

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Alternative, collaborative, complementary, integrative, natural, unconventional and holistic are terms that are used to describe medical and dental treatments that do not conform to mainstream/allopathic/western/orthodox health approaches. The multiplicity of terms is because of vast differences in practitioners' treatment approaches and is also an attempt to position such therapy in relation to standard/orthodox health practices. These terms will be used interchangeably in this paper although the reader should realize there may be subtle and, in some cases, significantly different implications when some individuals use one term in contrast to another. The diagnostic and therapeutic value of many of the treatments and medications prescribed in such alternative practices is often questioned or roundly criticized by generally accepted and widely published medical authorities, such as the American Medical Association, the American Dental Association, the Food and Drug Administration and state medical boards. However, Mark Blumenthal, an internationally respected botanical authority and executive director of the American Botanical Council has stated repeatedly that clinical studies shouldn't be a precondition to making limited claims for efficacy. If documentation is available, for example 3,000 years of anecdotal history for some herbs, then limited claims should be allowed. Blumenthal espouses the standard used by the Commission E doctrine in Germany, which is "the doctrine of reasonable

CDA JOURNAL, VOL 26, Nº3

certainty for efficacy and the doctrine of absolute certainty for safety."

Unconventional medical and dental practices, which may be viewed as conventional by those who subscribe to them, and certainly are conventional in some countries, such as their country of origin, offer a wide spectrum of treatments or treatment modalities (**Table 1**). A workable definition of unconventional or alternative dental practice is "those therapies neither taught widely in U.S. medical schools nor generally available in U.S. hospitals."

The public's interest in alternative health care has grown dramatically in the past few years. In a 1993 article, titled "Unconventional Medicine in the United States," Dr. David Eisenberg and colleagues reported the results of a 1990 telephone survey of U.S. adults.[1] Of the 1,031 individuals who completed the survey, 34 percent said they had used at least one unconventional therapy in the previous year, and one-third of those (11.2 percent) had seen providers of unconventional therapy. The latter patients made an average of 19 visits in the course of a year to such providers, mostly for the treatment of chronic illness. Dr. Eisenberg extrapolated the survey results to the U.S. population and concluded that "Americans made an estimated 425 million visits to providers of unconventional therapy vs. only 388 million visits to all primary care physicians. Based on a reported average charge of $27.60 per visit to alternative providers, Dr. Eisenberg's group estimated "expenditures associated with use of unconventional therapy in 1990 amounted to approximately $13.7 billion ($10.3 billion out of pocket), which is comparable to the $12.8 billion spent out of pocket annually for all hospitalizations in the United States. Thus, Dr. Eisenberg concluded that "both the frequency and use of unconventional therapy in the United States is far higher then previously reported."

TABLE 1

Systems of Medicine
Western
Herbal/folk
Homeopathy
Eastern (Chinese)
Ayurveda

TABLE 2

Alternative or Complementary Dental Product Categories
Natural standard products
Herbal products
Homeopathic products
Synthetic alternative products

A significant trend toward coverage of alternative care by health insurance companies is being driven by patient demand and cost differences favoring alternative care/self-care. Leading the way are insurers such as Oxford Health and Blue Cross/Blue Shield. Oxford Health surveyed its 5,500 employees and determined that 33 percent already use some form of alternative medicine, while 25 percent were interested in learning more about alternative treatments. In 1996, Oxford Health became the first health maintenance organization to offer comprehensive coverage for a range of alternative care providers without referral by a primary care physician.[2]

Examples of alternative health care practitioners typically include acupuncturists, chiropractors, massage therapists, yoga instructors, nutritionists, dietitians and naturopathic physicians, aromatherapists, guided imagery caregivers, and crystal therapy healers, to name a few. Knowledge about alternative medicine is slow getting into medical school curricula. Only 50 of the nation's 125 medical schools, including Harvard, Yale and Johns Hopkins, now offer courses in alternative medicine.[2]

The authors' interactions with their dental colleagues and their knowledge of dental school curricula reveal that alternative dental products and treatment modalities are rarely included in dental education. In part, this may be due to the fact that the trend in health care toward alternative therapeutic measures is occurring to a lesser degree in dentistry. Also, many alternative-care protagonists are squarely aligned against orthodox dentistry by being antifluoride or antimercury. A vocal minority of practitioners preach the toxic dangers of root canal fillings and the folly of periodontal surgery in salvaging teeth. Most holistic dental practitioners simply recommend alternative and natural dental products that are available through their practice, in health food stores or by mail order. Unfortunately, most of these products have little or no direct scientific basis for the specific oral health claims.

Currently available alternative dental products can be classified into four categories. The authors use the terms natural standard products, herbal products, homeopathic products and synthetic alternative products (**Table 2**) to characterize these groups.

This grouping was done by evaluating the numerous products available in health food and vitamin stores or by mail. Common treatment claims or ingredients were evaluated and groups became apparent. There is some overlap between some groups of products.

Natural Standard Products

The first group, natural standard products, is made up of traditional oral health products formulated from naturally derived components. For example, in natural toothpaste, the fluoride comes from fluorspar, a fluoride-containing mineral mined from the earth (but bicarbonate of soda or charcoal are equally good). The abrasive system, instead of

CDA JOURNAL, VOL 26, Nº3

being silicone or some other synthesized abrasive, is precision-ground, naturally occurring, calcium carbonate (chalk) mined from the earth. The thickener, instead of being a synthesized product such as methylcellulose, is carrageenan, a substance derived from seaweed. The sweetener, xylitol, is a relatively expensive product extracted from birch trees, as opposed to a synthesized compound, such as saccharin.

One of the best known and most widely advertised natural oral health product lines is Tom's of Maine. Close examination of its labeling shows documentation of the source for all of the ingredients in its toothpastes and mouthrinses. One of Tom's of Maine's natural toothpastes (spearmint) has received the ADA Seal of Acceptance. This acceptance is based on the anticaries efficacy of the fluoride content. There are other natural products such as First Teeth toothpaste from the Laclede Corp.; Euroteeth, a line of tooth powders from Europe; Eco-Dent's Daily Care (made from natural sea salt); and Weleda's all-natural toothpastes made with natural silica and calcium carbonate. Weleda's toothpaste also contains myrrh, used for its antiseptic, astringent, healing, anti-inflammatory and preservative properties. To the author's knowledge, none of the companies other than Tom's of Maine, have sought the ADA Seal of Acceptance for their products. Most of these natural standard products do not contain fluoride; and their therapeutic claims have not been well-substantiated, other than anecdotally. It is interesting to note that a number of products in this category combine natural inorganic components with natural organic or herbal components, such as Beehive Botanical's Propolis Toothpaste, thereby overlapping into the category discussed next.

Herbal Products

This next large class of alternative oral health products is termed herbal products. These products feature herbal sources as the main active ingredient. Echinacea, for example, is the most common herbal remedy available in the United States for infections.[3] This herb is classified as a coneflower. Most preparations are derived from Echinacea angustifolia and purpurea, usually utilized as a tincture or in powder form. It is often added to toothpastes and mouthrinses as a remedy for gum problems. Myrrh and echinacea are promoted for their antimicrobial action in toothpaste formulations by the noted therapeutic herbalist David Hoffmann in his book, The Complete Illustrated Holistic Herbal Element Books.[4] No modern studies have documented the efficacy of these products to treat any dental disease above and beyond the value of effective tooth brushing.

Studies during the past 15 years have focused on the polyphenols in green tea for their antibacterial and antiviral properties. In particular, Horibetal, 1991,[5] and Otake and colleagues, 1991,[6] have demonstrated that these polyphenolic compounds may protect teeth from caries by killing causative bacteria. Additionally, Makimura and colleagues, 1993,[7] proposed that those compounds inhibit bacterial collagenase activity. And Yu and colleagues, 1995,[8] reported that the polyphenols in green tea increase the acid resistance of human enamel. Though brewed green tea is considered to have these attributes, green tea is seldom added to oral health products. Another large group of oral products promoted for their antimicrobial properties contain malleleuca (tea tree) oil. These products are available in mouthwashes, toothpastes, toothpicks and lip balms. The pure oil is also available and can be applied with a toothbrush; however, it has a very pungent taste and strong aroma. Tea tree oil does have antimicrobial properties on bacterial cultures, but no studies document the efficacy of tea-tree-oil-containing dental products on oral disease. Some herbal products, such as the new Dental Herb Co. products called Tooth & Gum Tonic and Under the Gum Concentrate are promoted as anticaries and antiperiodontitis agents. The company states the products are "tissue conditioners" and "connective tissue rebuilders" that can reverse periodontal disease. There are no studies that the authors know of to support these claims. Other common herbal ingredients in oral health care products range from cariostatic agents to analgesics to antimicrobials to bleaching/scouring agents including aloe vera; aniseed bayberry; blue flag; burdock root; calendula; cayenne; chamomile; clevers; cloves; fennel; ginger; goldenseal; gotu kola; horsetail; licorice; marshmallow; myrrh; neem; peppermint; poke root; prickly ash; propolis; red sage; rosemary; strawberry and witch hazel; essential oils such as cinnamon bark, clove oil, eucalyptus, red thyme, and true lavender; and, for fetor ex ore (halitosis), fresh parsley, pulverized nettle leaves or watercress.

Documenting the efficacy of these herbal products is a daunting task, even if one has access to the premier source of herbal literature in the United States, the John Uri Lloyd Library in Cincinnati, Ohio, or is adept at searching for references on the World Wide Web (see **Table 3**, recommended sources); or has the financial capacity to purchase hundreds of books and periodicals from sources such as the Herb Research Foundation and American Botanical Council, publishers of the HerbalGram. The efficacy of these products, when documented, is almost always based on in vitro studies of single ingredients. Few studies document the clinical efficacy of dental formulations containing combinations of these

TABLE 3

Sources for Additional Information
1. American Botanical Council. Publishes HerbalGram, (512) 331-8868, www.herbalgram.org
2. Food and Drug Administration. Washington, D.C., (800) 532-444; www.fda.gov
3. Herb Research Foundation. Provides information packets on dozens of herbs. Web address: www.herb.org. Street address: 1007 Pearl St., Suite 2000, Boulder, CO 80302. Telephone/fax: (303) 449-2265/(303) 449-7849.
4. Herbal drugs and phytopharmaceuticals. A handbook for practice on a scientific basis. English translation by Norman Grainger Bisset from 2nd German edition (1989) edited by Max Wichtl. Medpharm, Stuttgart/CRC press, 1994.
5. Homeopathic Educational Services (Dana Ullman, MPH). Provides a myriad of medical and dental resources including books, tapes, software, practitioner registry, services available and research information.Web address: www.homeopathic.com. Street address: 2124 Kittredge St., Berkeley, CA 94704. Telephone: (800) 359-9051/(510) 649-0294.
6. PhytoNet. Set up and maintained by the Center for Complementary Health Studies, University of Exeter, Great Britain. Provides information on:
• ESCOP, the European Scientific Cooperative on Phytotherapy
• ESCOP members: National Associations of Phytotherapy in Europe
• The European commission BIOMED programme: Determining European standards of safe and effective use of phtyomedicines.
Web address: www.exeter.ac.uk/phytonet. E-mail: phytonet@exeter.ac.wk.
7. The Review of Natural Products (formerly the Lawrence Review of Natural Products). Published monthly by Facts and Comparisons, a Wolters Kluver Co., St. Louis, Mo., (314) 878-2515. A growing collection of peer-reviewed monographs that are periodically revised.
8. Quarterly Review of Natural Medicine. Published by Natural Product Research Consultants. Contains peer-reviewed annotated reviews and monographs on herbs, nutrition and natural health care, as well as book reviews. Donald J. Brown, N.D., editor in chief. Telephone/fax: (206) 623-2520/(206) 623-6340. E-mail: hprc@sttl.uswest.net.
9. The Protocol Journal of Botanical Medicine. Published quarterly by Herbal Research Publications. Ayer, Mass. Peer-reviewed and extensively annotated Herbal monographs and several sections each quarter covering various therapeutic approaches to specific diseases. Richard Scalzo, research director plus a distinguished editorial review board. Telephone/fax: (800) 466-5422\(800)717-1722.
10. The Alternative Medicine Source Book: A Realistic Evaluation of Alternative Healing Methods. By Steven Bratman, MD. Published by RGA Publishing Group, Los Angeles, 1997.
A new source of information about alternative health methods and products by a physician who incorporates some of them in his daily practice. Provides a balanced analysis with recommendations and lists numerous references and organizations.

compounds. However, there are notable exceptions, such as the combination of eucalyptol, thymol menthol (found in Listerine). Sanguinaria canadensis L. (found in Viadent), is a good example of a single ingredient herbal with documented clinical efficacy.[9]

Another group of herbs that deserves mention is the roots of several plants that have been used as toothbrushes for centuries in various parts of the world, including licorice root, marshmallow, alfalfa and horseradish. In some cases, sections of the root are chewed for 10 to 20 minutes and become spongelike, enhancing their physical cleansing/massaging action. Some of the roots are considered to have antimicrobial properties, although confirming controlled studies are not available. Dr. Hoffmann4 suggests slicing 5-inch sections of marshmallow root, peeling the ends, boiling them together with cinnamon sticks and cloves until tender, soaking them overnight in brandy, then drying them out. Before use, he recommends soaking the ends for a short time in hot water. Since all of the ingredients are in the root, no toothpaste is necessary.4 Though evidence of the clinical efficacy of the ingredients does not exist (i.e., the claims are anecdotal), the root will remove plaque, as would any physical abrasion with a "brush." There is an extensive body of literature on herb selection and self-preparation.

There is a huge variety of Chinese herbal preparations, as well as ayurvedic herbal preparations. Ayurvedic medicine is an ancient medical tradition found most commonly in India. Chinese herb formularies contain more than 1,000 formulae for dental and gingival/periodontal problems, including toothache, gingival swellings, caries, dry mouth, halitosis, oral ulceration and various types of stained teeth. An example of a Chinese herb in one of these formulae is pearl (zenzhu), which, in a 3 percent ointment, is promoted as possessing "strong wound healing properties" when applied to oral mucositis lesions occurring secondary to chemotherapy.10 Again, controlled clinical studies of the type used to document efficacy in Western medicine, have not been reported in the Western literature.

Homeopathic Remedies

A third category of oral health products is homeopathic remedies. These are based on the medical system of homeopathy. The basis of homeopathy is the Law of Similars (from the Greek words homoios, meaning similar, and pathos, meaning suffering). According to this belief, whereas a compound in a "high" dose can cause physical, emotional or mental signs and symptoms, a "tiny" homeopathic dose of that compound can stimulate a human response to reverse the pathology. Thus, the theory of homeopathy shares some similarities with the mechanism of vaccinations and the stimulation of the immune system.

A German chemist and physician, Samuel Hahnemann, developed this "like cures like" medical approach. In 1789, Hahnemann observed that excessive amounts of cinchona bark produced symptoms virtually identical to those of malaria, whereas minuscule amounts of the same bark reversed those symptoms. An expansion of those precepts were proposed by a student of Dr. Hahnemann's, Dr. Constantine Hering, the father of American homeopathy. Hering's Law of Cures states that healing progresses from the deepest part of the body to the extremities: from the upper part of the body to the lower; from the emotional to the physical, and from the most recent maladies to the oldest.

Homeopathy was practiced widely in the United States from the 1830s to the late 1920s. The founding of the American Institute of Homeopathy (1844) preceded that of the American Medical Association by three years. There were 22 homeopathic medical schools and nearly 100 homeopathic hospitals in the United States by the year 1900, counting among their adherents such notable figures as Nelson D. Rockefeller, Mark Twain and Thomas Edison.11 A survey of the medical literature from 1966 to 1990 revealed that 81 out of 107 controlled clinical studies demonstrated the effectiveness of homeopathic medical regimens for a wide variety of medical problems.[12]

A variety of homeopathic product manufacturers, including manufacturers of dental products, note that their products are FDA-accepted. Indeed, they are recognized as drugs; and they are regulated as to their manufacture, labeling and dispensing. Homeopathic products became FDA-accepted when the FDA was formed in 1936. Few studies have been done since 1936 to document the efficacy of ingredients used in homeopathic oral health products. A textbook on dental homeopathy titled A Textbook of Dental Homeopathy for Dental Surgeons, Homeopathists and General Medical Practitioners by Dr. Collin B. Lessell,[13] outlines the use of certain preparations for oral problems, such as mercurius vivus for tender bleeding gingiva and excessive salivation. The Board of Homeopathic Dentistry offers courses and a qualifying examination, and many members of the International Academy of Oral Medicine and Toxicology hold to these tenets.

There are a variety of product lines and approaches to treating oral diseases with homeopathic medicines, the oldest in America being Boericke & Tafel (established 1835), which makes more than 2,000 homeopathics. A new dental product line marketed enthusiastically to dentists through a multitiered marketing system is Orarex. These are homeopathy-based products from the Rexall Drug Co. There are a variety of other oral products containing homeopathic ingredients that are sold in health food stores. A group of homeopathics called "flower essences" are marketed over the counter. The best known of these is the Bach Flower Essences. Few controlled clinical trials have been conducted utilizing currently available homeopathic dental products to analyze their effect on oral disease.

Synthetic Alternative Products

The last category of alternative dental products is titled synthetic alternative products. These alternative dental products are made up of synthesized compounds, often derived from naturally occurring volatile essential oils. Examples include phenolic compounds such as thymol (from red thyme), eucalyptol, eugenol, menthol and phenol. They are promoted primarily as disinfectants. Phenol, per se, is an FDA-accepted product for "numbing oral mucosal surfaces," and has been employed empirically in numerous mouthwashes;[14] however the authors could find no documentation of its intraoral disinfecting efficacy. Therasol is a product whose active ingredient (C31G, a combination of N, N-alkyl dimethyl glycine and Ng N-dimethyl amino oxide) is natural but not derived from a volatile oil. The product is promoted as a treatment for periodontal disease. No in vitro human studies of product use are available to document its efficacy.

The above four categories make up the principle groupings of all alternative oral health care products within the scope of this paper. Some products may contain ingredients from several groups. As noted, most products have little to no research documenting their efficacy. When research is done, it most commonly shows that the active ingredient, when placed in a petri dish with the target organism, can kill that organism. One extrapolation that the company promoting the product urges the dental practitioner and consumer to make is that the target organism is the cause of a particular oral disease and that

TABLE 4

Stipulations of the Dietary Supplement and Health Education Act of 1994
No efficacy test required
Proof of safety not necessary
No manufacturing standards required
Claims must be substantiated (but manufacturer does not have to reveal evidence)
FDA approval for claims not needed

TABLE 5

Categories of Natural Products
Nutraceuticals -- naturally derived substances offering preventive or curative health/medical benefits.
Phytopharmaceutical -- plant-derived products used as prescription and nonprescription drugs
Functional food ingredient -- nutrient-rich concentrates used as food additives and dietary supplements
Dietary supplements -- standardized botanical extracts, tinctures, powder or tablet/capsule preparations

the manufactured product, containing the active ingredient, utilized as directed, will kill the target organism in the oral cavity and therefore resolve an oral disease. The reliability of such extrapolations is notoriously poor at best. Many problems can occur, including degradation of the active ingredient during manufacturing or storage, and an inability of the product to reach the site of action. Another extrapolation the user is forced to make is that the peculiar combination of ingredients have a synergy of action. Controlled clinical trials using these products in the oral cavity compared to an inactive product provide the best evidence of efficacy and safety. Such studies on almost all alternative oral health products and their purported active ingredients do not exist.

The natural product market is growing rapidly,[2] and it is estimated that 16 percent of the population use herbs. Such natural and herbal therapies are widely accepted in Europe, and the botanical herbs industry has grown by 15 percent during the past several years. In the United States, the Dietary Supplement and Health Education Act of 1994[15] (**Table 4**) has spurred growth in the herbal industry, in part because these products do not need as rigorous FDA approval as prescription drugs.

Some authors have characterized the natural products category of compounds, including oral health products, as nutraceuticals (**Table 5**). Nutraceuticals are defined as naturally derived substances offering preventative or curative health/medical benefits. Nutraceuticals can be subdivided into cosmoceuticals (natural beauty aids), phytopharmaceuticals, (plant-derived products used as prescription and nonprescription drugs), functional food ingredients (nutrient-rich concentrations used as food additives) and dietary supplements (standardized botanical extracts, tinctures, powders or tablet/capsule preparations.) These products are usually manufactured and sold in accordance with the Dietary Supplement and Health Education Act. No matter what the bold print on the label claims, the fine print on the labeling should note that the product is considered a dietary supplement and that no therapeutic claims are made or implied. The literature about the product, which is distributed separately can make structure/function claims that are truthful, not misleading and do not purport to cure, treat or mitigate disease. The literature should note that the claims have not been evaluated by the FDA.

The dietary act also states that no efficacy testing is necessary and that proof of safety is not necessary for these products. There are no required manufacturing standards; however, the industry is rapidly promulgating a "Good Manufacturing Practices" doctrine. The dietary act also states that the claims must be substantiated, but it notes that manufacturers do not have to reveal the evidence for this substantiation. Furthermore, it notes that the FDA approval for claims is not required.[15] A new product that is a good example within this category is Breath Assure. It is a combination of parsley oil and cottonseed oil and is designed to control halitosis. Close reading of the packaging will note that it is classified as a dietary supplement. The manufacturers note that they do not know the mechanism of action of the product; and, though they have studies documenting its efficacy, they are not available for scrutiny[16] (personal communication to one of the authors).

Conclusion

Alternative, natural dental products continue to proliferate rapidly. Dentists and dental hygienists should be knowledgeable about these traditional and emerging, preventative and therapeutic products because a large number of patients use them or intend to do so. These patients may rely on dental professionals for sound advice in this area. There are a number of efficacious products available. As noted above, some products made with all natural ingredients by Tom's of Maine, spearmint and cinnamint toothpastes, have received the ADA Seal of Acceptance, and more may follow. At the same time, numerous natural dental products are available with no research supporting their efficacy. The decision regarding their use must be made by patients and/or their dental health providers and should be based on their oral health needs and the availability of scientific documentation as to their safety, at least, as well as their efficacy.

There is growing interest in alternative medicine and dentistry and the use of alternative dental products. Dentists and hygienists should have some knowledge about these products. This will enhance their credibility as knowledgeable and empathic health care providers.

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Over-the-Counter Products for Oral Ulcerations

By William M. Carpenter, DDS, MS, and Sol Silverman Jr., MA, DDS

ABSTRACT Over-the-counter products can be useful and effective in alleviating the pain from ulcerations of the oral mucosa. This article reviews over-the-counter medications that are available to treat ulcerative lesions. Among the categories included are covering agents, local anesthetics, and mouthrinses.

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Ulcerations of the oral mucosa are a frequent occurrence as a result of many etiologic factors. An ulcer (loss of the surface epithelium) may be of a primary type (no previous lesion) or secondary to a previous lesion (vesicle or bulla).[1] The differential diagnosis would include those conditions shown in **Table 1**. This discussion will not involve recurrent herpes labialis (cold sores).

Since so many different pathologic conditions may present in an ulcerative state and require different therapeutic/management approaches, the most important first step for treatment is an accurate diagnosis. This is often a very difficult task, and many diagnostic studies may be required.[2]

Once a working or definitive diagnosis is established, there are many effective and specific prescription medications or treatments that may be indicated. However, a number of ulcerative lesions require only a period of time until the epithelium can regenerate. See **Table 1**.[1-4]

During this time, over-the-counter products may be useful and effective in alleviating the pain involved regardless of the etiologic agent. The advantages of an OTC product are the cost, availability and lack of side effects. The main side effect, if the instructions are properly followed, would be a hypersensitivity to one of the ingredients.

CDA JOURNAL, VOL 26, Nº3

TABLE 1

Traumatic events
Physical
Thermal
Chemical
Vesicular disease
Microbiologic (usually viral)
Immunologic
Recurrent aphthae
Bullous disease
Hypersensitivity reactions
Leukopenic ulcers secondary to:
Immunosuppression
Drug-induced toxicities
Radiation-induced ulcers
Microbiologic
Fungal
Baterial
Neoplastic
Benign
Malignant

OTC Products[3-6]

Localized Use (Direct Application)

Covering Agents

Several products are available that are covering agents (emollients). They act to ameliorate the pain by forming a protective covering.

The two main products in this category are:

- Orabase (Colgate Oral Pharmaceutics) – an emollient paste composed of sodium carboxymethyl cellulose with pectin, gelatin, sugar gum, cellulose gum and tragacanth gum dispersed in a plasticized hydrocarbon gel composed of 5 percent polyethylene in mineral oil.
- Zilactin (Zila Pharmaceuticals) – a film-forming liquid composed of a hydroxypropyl cellulose and 10 percent benzyl alcohol.
- These two products have been utilized for many years, and both are effective. However, some personal preferences exist, both with patients and practitioners. Both products have optionally available an anesthetic, benzocaine, to provide additional relief, if pain is severe.

Local Anesthetics

- Orabase - B – Benzocaine 20 percent.
- Zilactin - B – Benzocaine 10 percent.

In addition, another product is available.

- Orabase - B Gel – Benzocaine 15 percent w/w as the active ingredient in ethylcellulose with ethyl alcohol, 57 percent w/w propylene glycol, salicylic acid, tannic acid and sodium saccharin.

Other commercially available products containing benzocaine as the active ingredient are:

- Anbesol Liquid (maximum strength) – Benzocaine 20 percent, alcohol 60 percent and saccharin (maximum strength).
- Anbesol Liquid – Benzocaine 6.4 percent w/v, phenol 0.5 percent, potassium iodide, alcohol 70 percent v/v povidone iodine, camphor, glycerin and menthol.
- Anbesol Gel (Whitehall Labs) – Benzocaine 6.4 percent and 0.5 percent phenol, carbomer 934P.
- Senso-gard (Block Drug Co.) – Benzocaine 20 percent, methylparaben, polycarbophil, polyethylene glycol, propylparaben and sorbitan mono-oleate.
- Tanac (Del Pharmaceuticals) – Benzocaine 10 percent and benzalkonium chloride 0.12 percent, polyethylene glycol 400, water, sodium saccharin, propylene glycol and tannic acid.
- Orajel Mouth-Aid (Del Pharmaceuticals) – Benzocaine 20 percent, benzalkonium chloride 0.02 percent, zinc chloride 0.1 percent, allantoin, carbomer, edentate disodium, peppermint oil, polysorbate 1.0, saccharin, sorbic acid, polyethylene and propylene glycol, propyl gallate, water, povidone, and stearyl alcohol.
- Kank-A (Blistex Inc.) – Benzocaine 20 percent, cetylpyridium chloride 0.5 percent, mgm, 1 gm benzyl alcohol with benzoin tincture, castor oil, dimethyl isosorbide, saccharin, ethylcellulose, tannic acid and propylene glycol.
- Medadyne (Dal-Med Pharmaceuticals) – Benzocaine and methylbenzethonium chloride, methol camphor, benzyl alcohol, chlorothymol in a hydro-alcoholic base 61 percent.
- Hurricaine Liquid and Gel (Beutlich Pharmaceuticals) – Benzocaine 20 percent, polyethylene glycol flavoring.
- One other product that has been in use for a long time, principally for sore throats but also for relief of pain in mouth sores, is a phenol product.
- Vicks Chloraseptic sore throat spray (Procter & Gamble) – Active: phenol 1.4 percent; inactive: D&C green No. 5, D&C yellow No. 10, FD&C green No. 3, flavor, glycerin, purified water, saccharin sodium.

Oxygenating Agents

Hydrogen peroxide is a major ingredient in several products as a mouthrinse or for direct application. The oxygenating effect helps to debride the ulcer and is a mild antibacterial agent.

- Peroxyl Mouthrinse (Colgate Oral Pharmaceuticals) – 1.5 percent hydrogen peroxide in an aqueous solution with ethyl alcohol 6 percent v/v sorbitol solution 70 percent, polysorbate 20 methyl salicylate, menthol, pluronic F108 and sodium saccharin.
- Peroxyl Oral Spot Treatment Gel (Colgate Oral Pharmaceuticals) – 1.5 percent hydrogen peroxide in a gel base.
- Other oxygenating products are

available that contain carbamide peroxide as the active ingredient:

- Cankaid Rinse (Dickinson Co.) – Carbamide peroxide 10 percent in anhydrous glycerol, citric acid monohydrate, sodium citrate dihydrate, and edentate (disodium).
- Gly-Oxide (Smith-Kline Beecham) – Carbamide peroxide 10 percent, citric acid, glycerin, propylene glycol, sodium stannate and water.
- Periolav (Spectrumed, Inc.) – Carbamide peroxide 10 percent in anhydrous glycerol.
- -Orajel Perioseptic spot treatment (Del Pharmaceuticals) – Carbamide peroxide 15 percent in anhydrous glycerin, citric acid, edentate disodium, methylparaben, propylene glycol, water, sodium chloride, sodium saccharin.

Cauteries and Antiseptics

Other products are available that are chemical cauteries and mild antiseptics. Examples of this type of product are:

- Ora - 5 (Premier Dental Products Co.) – Copper sulfate, iodine, potassium, iodide and alcohol 1.5 percent.
- Oralief (H.T.C. Co.) – Zinc chloride, phenol, cetylpyridium chloride, alcohol, and glycerin.

Mouthrinses

There are several ulcerative conditions that are multifocal and/or diffuse and require a topical medication in a more easily applied form than direct application. These are available in liquid form and act as a covering agent. They can be swished and expectorated.

One combination is available as separate medications over the counter and can be mixed by the patient:

- Diphenhydramine hydrochloride (Benadryl) syrup (4 ounce). Mix equal parts Kaopectate liquid (12 ounce) or Maalox suspension (12 ounce). Sig: Rinse for one minute with 1 teaspoonful and expectorate. Repeat every two hours or at mealtimes.

If more of an anesthetic effect is desired, Hurricaine liquid may be added. (When topical anesthetics are used, patients should be cautioned concerning a reduced gag reflex and the need to avoid aspiration.)

- Biotene Mouthwash (Laclede Products) – Lysozyme (40 mg) lactoferrin (15mg) glucose oxidase 2,500 units, lactoperoxidase 2,500 units, calcium lactate, sodium benzoate, benzoic acid, propylene glycol, hydroxyethol cellulose, aloe vera, peppermint, water, xylitol hydrogenated starch.
- Orajel Perioseptic (Del Pharmaceuticals) – Hydrogen peroxide 1.5 percent, edentate disodium ethyl alcohol (4 percent v/v), methyl salicylate methylparaben, phosphoric acid, poloxamer 338, water, sodium saccharin and sorbitol.
- Amosan (Oral-B Labs Inc.) – Sodium peroxyborate monohydrate buffered with sodium bitartrate.

Summary

These OTC medications have been employed successfully for many years in alleviating the pain associated with oral lesions and are major agents in the arsenal of the practitioner. The lack of prospective controlled studies make outcome assessments difficult, and none of these has been shown conclusively to be other than palliative. Therefore preferences and benefits are variable in a population. Furthermore, it must be understood that an ulcer may be the manifestation of a serious disease that requires a more definitive treatment. Therefore, if lesions do not show any evidence of healing in a matter of a week, a definitive diagnosis must be ascertained and a more specific treatment rendered.

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Over-the-Counter Mouthrinses

By Stuart L. Fischman, DMD

ABSTRACT Mouthrinses have traditionally been used for cosmetic purposes. Therapeutic products are now available, many of which are sold over the counter. Consumers rely on dental professionals for guidance in the selection of a mouthrinse. The various product categories are reviewed and criteria for patient and/or consumer selection are suggested.

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Freshening bad breath has been the traditional use for mouthrinses.[1] The 1996 market for such products is estimated at $662 million. In addition to the traditional cosmetic types, therapeutic mouthrinses are now available.

The active ingredients of most mouthrinses include quaternary ammonium compounds, boric and benzoic acids, and phenolic compounds.[2] Commercial sales of a rinse are closely related to taste, color, smell and the pleasant sensation that follows use. The pleasant sensation is often enhanced by the addition of astringents. Commonly used astringents are alum, zinc stearate, zinc citrate, and acetic or citric acids. Zinc salts have been added to mouthrinses as an antiplaque ingredient. Alcohol in the mouthrinse is used as a solvent and taste enhancer.

Halitosis

Breath, not health, is often the first priority where use mouthwash is concerned. Consumers most commonly use mouthrinses to chemically treat oral malodor. Almost two-thirds of all mouthwash users say they rinse mainly to freshen their breath; curbing plaque and gum disease are a distant second.[3] Oral malodor has been a neglected research area. The first scientific symposium on halitosis research was not held until 1991. Identifying the cause of halitosis and developing an appropriate treatment plan can be difficult. Published studies have demonstrated that oral malodor usually derives from the mouth itself and may be reduced following oral hygiene. To motivate improvement in oral hygiene, dental professionals should advise patients that bad breath

CDA JOURNAL, VOL 26, Nº3

may result from microbial putrefaction within the mouth. Rosenberg[4] notes that "bad breath is a cause of concern, embarrassment, and frustration on the part of the general public. Oral malodor, whether real or perceived, can lead to social isolation, divorce proceedings, and even 'contemplation of suicide.'"

Many things can help oral malodor, but nothing is completely effective against bad breath because the causes are too diverse. In addition to the bacteria that cause "morning breath," common causes of oral malodor include:

- Smoking, chewing tobacco and drinking alcohol;
- Aromatic compounds in foods such as garlic and onions, which enter the bloodstream, are carried to the lungs, then exhaled;
- Gum disease, especially when accompanied by bleeding gums; and
- Respiratory-tract infections, such as chronic bronchitis or sinusitis with postnasal drip.

Instead of relying totally on mouthwash to mask the problem, a person with chronic bad breath should be examined by a dentist and, possibly, a physician.

To combat odors from such divergent sources, many mouthwashes rely in part on their ability to cover odors with pleasant-smelling ingredients. This effect is often quite temporary. Even the best cosmetic mouthwashes give out fairly quickly. Breath tests taken one and two hours after panelists rinse typically fail to distinguish any products as particularly effective. On the other hand, breath freshening effects from mouthrinses that also have strong antiseptic activity persist longer than those relying solely on odor masking because these mouthrinses also affect the bacteria that produce malodorous compounds.

There are methods that permit the quantitative assessment of bad breath and therefore should be able to verify "breath freshening" claims.[5] To determine the relative contributions of masking and antisepsis to overall anti-odor effectiveness of a product, it is necessary to simultaneously measure the odor of the mouth, the concentration of malodorous microbial metabolites in mouth air, and populations of oral odorigenic microorganisms in each subject while holding other factors constant.

Antiseptic mouthwash can be highly effective in depressing all determinants of oral malodor. While the effects of the treatments may differ in magnitude, the malodor determinants are well-correlated for all treatments at all times with one important exception: In the first sample taken after antiseptic mouthwash use, oral malodor was substantially less than predicted from volatile sulfur or bacterial levels.[5] Analysis of these data demonstrates that re-odoration is important to the overall activity of the product for only about 30 minutes after treatment; and, at post treatment times of 60 to 180 minutes, the anti-odor activity of the product is due to its antimicrobial action.

Essential Oils

Listerine antiseptic, a combination of phenol-related essential oils, thymol and eucalyptol, mixed with menthol and methylsalicylate, is the first over-the-counter, or OTC, antiplaque and antigingivitis mouthrinse to be accepted by the ADA Council on Scientific Affairs.[6] Listerine has been marketed for more than 110 years. Patients are directed to rinse twice daily with 20 ml of Listerine for 30 seconds, in addition to their usual oral hygiene regimen. Microorganisms do not develop a resistance to the antimicrobial effects of essential oils. Two generic versions of original Listerine have also been granted the ADA seal and are marketed under numerous trade names.[7]

In long-term clinical trials, Listerine has been shown to reduce both plaque accumulation and severity of gingivitis by up to 34 percent.[6] Microbial sampling of plaque in these trials has demonstrated no undesirable shifts in the composition of the microbial flora. As with chlorhexidine, rinsing with Listerine per se is unlikely to be effective in treating periodontitis because the solution does not reach the depths of the periodontal pockets. Irrigation studies, using irrigator tips designed to deliver solutions subgingivally, suggest that Listerine may have some value as an adjunct to mechanical therapy.

Herbal Extract -- Sanguinarine

Viadent rinse and toothpaste each contain sanguinaria, an extract of the bloodroot plant. Several long-term studies of the toothpaste showed no significant plaque reduction. One six-month study in which subjects used both the toothpaste and mouthwash twice daily showed a 21 percent reduction in plaque and a 25 percent reduction in gingivitis.[8]

Quaternary Ammonium Compounds

This group of cationic surface active agents has been in use for many years. The most commonly used member of the group is CPC or cetylpyridinium chloride, the active ingredient in Cepacol. One six-month study reported a 14 percent reduction in plaque, accompanied by a 24 percent reduction in gingivitis. Scope and some generic mouthwashes also contain cetylpyridinium chloride.

Oxygenating Agents

Agents such as peroxides and perborates have been used in the short-term treatment of acute necrotizing gingivitis and

pericoronitis. Several oxygenating rinses, such as those containing chlorine dioxide (e.g., Oxyfresh), are marketed as breath freshening agents. However, little scientific data demonstrating efficacy is available.

Fluorides

Some short-term studies indicate that stannous fluoride is a more effective antiplaque agent than sodium fluoride. Stannous fluoride (SnF2) used as a gel or rinse may provide a reduction in plaque and/or gingival inflammation. Contrary reports are found in the literature, and considerable reservation has been voiced on the efficacy of SnF2 as an anti-plaque/gingivitis agent.8 It may provide a significant anticaries benefit in special patient populations, such as those with orthodontic appliances, xerostomia or bulimia.

Surfactants

A detergent prebrushing rinse, Plax, contains sodium lauryl sulfate and sodium benzoate. There is a disparity in studies of the clinical efficacy of this product. A reduction in plaque has been reported in some studies, while others show no difference between the rinse and a placebo.[8]

Preprocedural Rinsing

For the dental professional, it may be important for patients to use a mouthrinse prior to aerosol-generating procedures. Unless an effective dry-field technique is used, the bacterial aerosol generated by a high-speed turbine in 30 seconds is roughly equivalent to the patient sneezing in the dentist's face. A study by Wyler[9] and colleagues found that even a preliminary water rinse temporarily reduced the bacterial aerosol population by 61 percent, brushing alone by 85 percent, and an antibacterial mouthrinse by 97 percent. Fine10 and colleagues, using a simulated office visit model, showed that preprocedural use of an antimicrobial mouthrinse (Listerine) resulted in a 93.6 percent reduction in the number of viable bacteria in a dental aerosol produced by ultrasonic sealing. The effect of this reduction on actual disease transmission has not been determined.

Xerostomia Mouthrinses

Many people experience dry mouth (xerostomia) that can be traced to several possible causes, such as damage to the salivary glands following radiation therapy for head and neck cancer, Sjögren's syndrome, and the use of tranquilizing drugs, especially the tricyclic antidepressants. In such cases, the mucous membrane is continually dry and uncomfortable. To ameliorate the dryness, artificial salivas have been developed to be used ad libitum by the patient to moisten the mucous membrane.[11]

Because xerostomia is correlated with an increased caries incidence, the rinses usually contain fluoride as well as chemical compounds in concentrations that closely parallel those of saliva. The rinses that contain fluoride may, in reality, be remineralizing solutions. Several artificial salivas have been accepted by the ADA, among which are Glandosane, Moi-Stir, Salivart, and Xero-Lube.[7]

Conclusion

In addition to the traditional cosmetic use, therapeutic mouthrinses are available. There are many OTC formulations with a variety of active ingredients, including quaternary ammonium compounds, boric and benzoic acids, and phenolic compounds. The conscientious dental professional should look to the contemporary literature for guidance in making recommendations.

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In-Ceram Fixed Partial Dentures: Three-Year Clinical Trial Results

By John A. Sorensen, DMD, PhD; Seung-Koo Kang, DDS; Tony J. Torres, CDT; and Helmut Knode, ZTM, DMD

ABSTRACT In-Ceram is a sintered, high alumina content, glass infiltrated ceramic core material reported to have sufficient strength for all-ceramic fixed partial dentures. While Vita/Vident recommends that In-Ceram should be used only for anterior FPDs, the purpose of this study was to push the sintered alumina material to its limits by testing posterior FPDs with premolar and molar pontics. This prospective clinical trial tested the longevity of 61 three-unit In-Ceram alumina FPDs. The failed specimens were analyzed to determine factors contributing to failure. The abutment teeth were prepared for full crown retainers with shoulder margins and 1.3 mm of axial reduction. All FPDs were cemented with an encapsulated glass ionomer.

None of the patients reported postcementation sensitivity. During the three-year period, seven FPDs fractured through the connector area. By location of the pontic, failure rates were 0 percent for anteriors, 11 percent for premolars and 24 percent for molars. Based on the results of this clinical study at the three-year point, In-Ceram alumina can be reliably utilized for anterior FPDs as indicated by a 100 percent success rate. The findings do not support the use of In-Ceram alumina for posterior FPDs as was advised by the porcelain manufacturer. Glass ionomer cement can be predictably used to cement In-Ceram FPDs with few clinical side effects.

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Dr. Michael Sadoun in 1988 reported the development of a new approach to the fabrication of all-ceramic fixed prostheses.[1] The master dies are duplicated in a special plaster with a mold to shape the undersurface of the pontic (**Figure 1**). This technique was taken from the ceramics manufacturing industry using a process called "slip casting" whereby a fine particle size high-alumina content powder is mixed with a special liquid and applied as a slip material to the plaster dies.

As the slip is applied to the die, moisture is absorbed into the stone agglomerating or tightly packing the particles onto the stone (**Figure 2**). The coping is carved to the desired dimension and sintered at approximately 1,140 degrees Celsius in a special oven over an 11-hour firing cycle. The particles fuse at the points of contact producing an organized, highly stable crystalline structure (**Figure 3**). From the sintering procedure, the moisture is driven from the die material causing the die to shrink away from the coping, eliminating the need for aluminum oxide abrasion devestment (**Figures 4 and 5**). At this stage, the coping is white and opaque and has low strength. A process developed by Dr. Sadoun called "infiltration glass firing" is

CDA JOURNAL, VOL 26, Nº3

then performed. At elevated temperatures, this glass material -- applied as a slurry on the external surface of the coping -- flows into the interstitial spaces by capillary action (**Figure 6**). An altered refractive index results in a translucent substructure with the selected shade inherent to the high strength core material (**Figure 7**). The patent rights[2] to this material were then transferred to Vita Zahnfabrik (Bad Sackingen, Germany) and after several years of research and development was launched on the market as In-Ceram. The exact fabrication procedures are presented in a technical journal.[3]

In vitro tests have demonstrated excellent material properties for fixed prosthodontics. A three-point bend test recorded flexural strengths of 446 MPa, nearly three times stronger than any of the other ceramic tested.[4] Cross-sectional marginal fidelity studies where crowns were indirectly fabricated and cemented on their respective dies yielded mean vertical marginal discrepancies of only 24 m for In-Ceram crowns while metal-ceramic crowns with a metal collar had marginal discrepancies of 27 m.[5,6] The best marginal fit was achieved with a shoulder margin, but even a feather-edge or shoulder-bevel margin (not recommended for all-ceramic crowns) produced excellent marginal fit of 67 m.[5] With similar experimental methodologies, three-unit posterior In-Ceram FPDs yielded a mean vertical marginal discrepancy of only 58 m.[7] This is excellent marginal adaptation considering the complexity in seating an FPD on two abutments during cementation. Unlike metal-ceramic FPDs, which have metal substructure distortion resulting from the porcelain firing procedure yielding a degradation of the post ceramic firing fit,[8-10] the In-Ceram material is highly stable; and its fit does not deteriorate with veneer porcelain firings.

Many problems inherent to metal-ceramic restorations can be overcome with metal-free ceramics. The advantages of an all-ceramic FPD include:

- Greatly improved esthetics from light transmission through the core material and enhanced shade match between core materials and veneering ceramic (**Figures 8 and 9**);
- Greatly reduced thermal conductivity resulting in reduced temperature sensitivity and adverse pulpal responses;
- A radiolucent material, which allows for greater effectiveness of diagnostic radiographs;
- Reduced iatrogenic periodontal disease due to diminished plaque accumulation from the inherently smoother properties of ceramic compared to the metal-opaque-porcelain junction;
- Reduced iatrogenic periodontal disease due to the fact that better contours can be achieved compared with typical overcontouring of metal-ceramic crown margins; and
- Reduced health hazard because all-ceramic bridge materials are essentially inert, while more than 80 percent of dentists in the United States use base metal alloys containing nickel, beryllium and chromium.

In-Ceram restorations gain their high strength from the core material and do not rely on the adhesive cementation technique for strengthening of the restoration like other all-ceramic crown systems. IPS Empress (Ivoclar North America, Amherst, N.Y.)11 and OPC (Jeneric/Pentron, Wallingford, Conn.)[12] must be adhesively cemented to achieve maximum strength for clinical longevity. In-Ceram is the only all-ceramic system that can be handled clinically and cemented like a metal-ceramic restoration. **Figure 10** illustrates how the dynamic seating method can be used for cementation of an In-Ceram crown similar to a metal-ceramic crown.

Dr. Sadoun worked with a number of practitioners in France to clinically test his new ceramic. Their work resulted in success rates of 100 percent for single anterior and posterior crowns. For FPDs, they observed a 100 percent success rate for anteriors and a 91 percent success rate for posteriors.1 After analyzing the clinically failed specimens, he determined that most of the posterior FPD failures occurred at the occlusal-proximal line angles of the abutments adjacent to the pontic. They then modified the posterior FPD preparation design to include preparation of small boxes on the interproximals adjacent to the pontic. After 1.5 years of clinical testing, they had a success rate of 100 percent.[13] An in vitro study recorded a 30 percent higher breaking strength of In-Ceram posterior FPDs with the proximal box design.[14]

Since metal-ceramic FPDs are the standard of care in practice, their clinical survival rate should be used as the criterion for new all-ceramic systems. Considering the extent of worldwide usage of metal-ceramic restorations, relatively little information is available on the survival rate and average service times of esthetic fixed prostheses in clinical practice. The fact that many dental insurance companies will pay for the fabrication of a new FPD every five years is testament to the low state of the art. The following clinical studies yielded positive results with relatively low failure rates. Leempoel and colleagues15 studied the survival rate of crowns in 40 Dutch general practices. For 1,323 anterior metal-ceramic crowns, survival rates at five years were 95 percent and at 10 years were 82 percent. For 2,011 premolar metal-ceramic crowns, survival rates at five years were 98 percent and at 10 years were 97 percent. A failure rate of 2.8 percent for metal-ceramic

CDA JOURNAL, VOL 26, Nº3

crowns was observed over a seven-year period at the University of Zurich.[16]

Coornaert and colleagues17 followed 2,181 metal-ceramic units over seven years and observed a 2.4 percent failure rate. The follow-up rate was 85 percent during the seven-year study with most failures occurring within one year after cementation. Inadequate gold framework thickness resulting in porcelain fracture near the gingival margin and framework fracture through the FPD connectors were most often the source of failure. These failures were indicative of efforts to improve the esthetics by reducing the dimensions of the metal framework in order to increase the porcelain thickness. Leempoel and colleagues18 evaluated 86 FPDs with 213 restored abutments in general practice over seven years and found a 4.4 percent failure rate.

To summarize the data on the few clinical studies that have been performed -- most of them well more than a decade ago -- the metal-ceramic prostheses failure rate at approximately seven years was about 2.5 percent to 6 percent. An equally low failure rate of In-Ceram FPDs is expected if this system is to be accepted for general clinical use.

The Vita/Vident company (Brea, Calif.) recommends that In-Ceram be used for single anterior and posterior crowns as well as anterior three-unit FPDs. It does not recommend its application for posterior FPDs. The purpose of this prospective clinical trial was to push this material to its limits by testing both anterior and posterior FPDs. A secondary purpose was to determine the factors that contributed to any failures. This paper is primarily concerned with longevity factors of the In-Ceram FPDs.

Materials and Methods

Patients were recruited from the greater Los Angeles area and treated at the School of Dentistry Clinical Research Center of the University of California at Los Angeles. Qualification requirements for acceptance into the study were that subjects had a minimum of 20 teeth, did not wear a complete denture, had at least moderately good oral hygiene, had no active periodontal disease, had one missing tooth needing replacement, and had teeth or fixed prostheses opposing the pontic space. Multiple three-unit FPDs could be placed in the same subject. Potential subjects were not rejected if they had a history of bruxism. Since bruxers are a normal part of the dental population, it was believed they should be included in the study. Location and extent of wear facets as well as type of contact in lateral excursions were recorded. Patient subjects were given informed consent and all Human Subject Protection Committee guidelines were followed.

Tooth Preparation

All teeth were prepared with a flat-ended diamond aiming for 1.3 mm of axial reduction and 1.5 to 2 mm for incisal or occlusal reduction. This is the same amount of reduction or less than needed for metal-ceramic FPDs. The margin design was a shoulder configuration with a rounded axial-gingival line angle. The shoulder margin design provides the greatest strength and best marginal fit.[5] A flat-ended diamond can penetrate the tooth to varying degrees and still produce a shoulder configuration free of lipping. The bulk reduction was performed with a flat-ended diamond, followed by refinement of the margin with tissue-protecting end cutting burs. The margins were finalized with hand instruments to achieve as smooth, clean and linear a finish line as possible.

Figure 11 illustrates the standard abutment tooth preparation for an anterior FPD with full circumferential shoulder margins. The anterior FPD was then cemented (**Figure 12**).

A modified abutment tooth preparation design was used for posterior FPDs. Full circumferential shoulder margins were prepared with the addition of small boxes on the interproximals adjacent to the pontic. Often these can be placed where previous fillings had been. These abutment tooth box design features serve to increase the bulk of core material at the proximal-occlusal line angle (**Figure 13**). **Figure 14** shows the cemented posterior FPD.

Margins on posterior FPDs were placed either equi- or supragingival when possible and extended subgingivally when needed for establishment of margins on sound tooth structure or replacement of existing fixed prostheses. Anterior FPD margins were placed just below the crest of the gingiva when esthetic margins were needed or otherwise on sound tooth structure equigingivally.

Gingival displacement was achieved by placement of a No. 2 Gingibraid cord containing 0.65 mg/inch of aluminum sulfate in the sulcus of the abutment teeth for 10 minutes. The cord was then moistened with Hemodent (ESPE, Seefeld, Germany) and removed; the sulcus was dried and a vinylpolysiloxane (Reprosil, Caulk, Dentsply, Milford, Del.) impression material syringed around the abutment teeth and followed by seating of the impression tray with a heavy body vinylpolysiloxane impression material. After seven minutes of setting time, the impression tray was removed. Opposing alginate impressions were made and interocclusal records made when needed. A provisional restoration was fabricated from acrylic resin with a vacuum matrix and cemented with calcium hydroxide (Dycal, Caulk).

Figure 1. Master die duplicated in a special plaster with a mold for the pontic.

Figure 2. Moisture absorbed into die stone agglomerating or packing alumina particles.

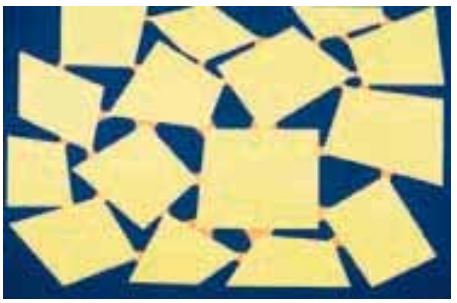

Figure 3. During sintering the alumina particles fuse together at points of contact producing a highly stable, organized crystalline structure.

Figure 4. FPD substructure is carved to desired dimensions.

Figure 5. Substructure has been sintered. Note how moisture has been driven off and the die has shrunk away from core.

Figure 6. At elevated temperatures, infiltration glass moves inside from external surface to fill air spaces between particles by capillary action.

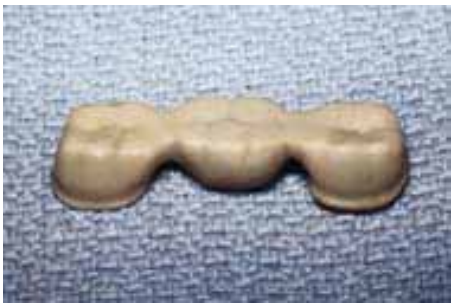

Figure 7. Glass infiltrated FPD substructure with translucency increased and shade conferred.

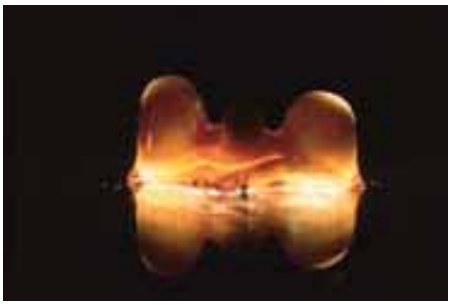

Figure 8. Transillumination reveals increased translucency resulting from glass infiltration procedure.

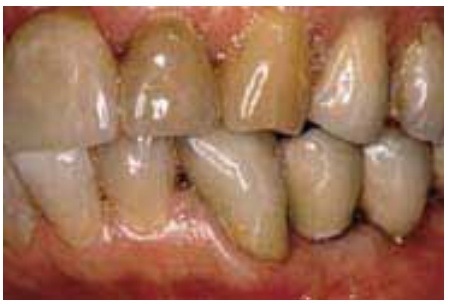

Figure 9. In-Ceram FPD Nos. 8 through 10 demonstrates translucency even with a Vita shade A5. Empress crown No. 22 for comparison.

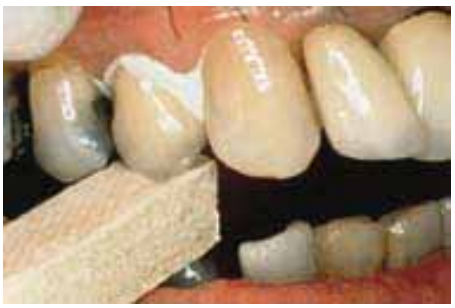

Figure 10. Dynamic seating of In-Ceram crown for cementation.

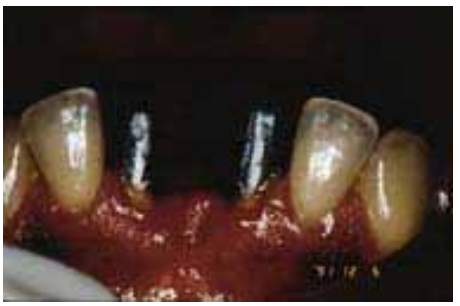

Figure 11. Standard shoulder tooth preparation design for anterior abutments.

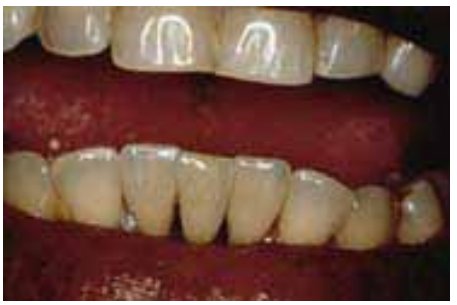

Figure 12. Cemented In-Ceram FPD.
Tooth Preparation

Figure 13. Posterior In-Ceram FPD with increased bulk of core material created by the proximal box preparations.

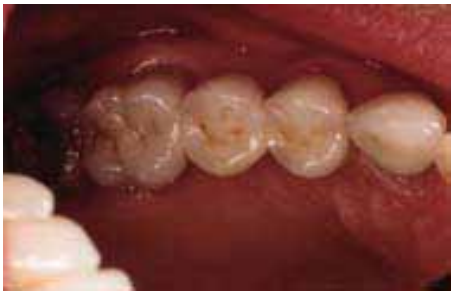

Figure 14. Cemented In-Ceram FPD Nos. 3 through 5.

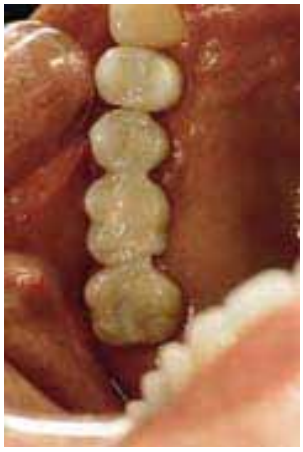

Figure 15. Clinical presentation of fractured FPD through posterior connector.

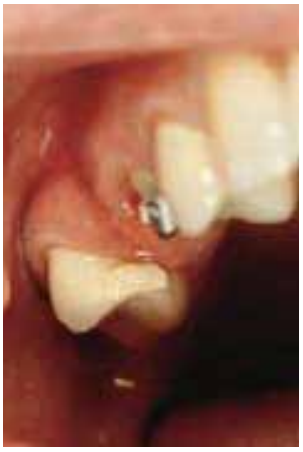

Figure 16. Small occlusal-gingival dimension of connector due to gingival tissues and occlusal contact on connector area.

FPD Fabrication Techniques

The impressions were poured in an improved die stone (Die-Keen, Modern Dental Materials Inc., St. Louis) and mixed according to manufacturer's specifications. The dies were pinned with the PinDex System (Whaledent, New York), sectioned and trimmed. Three layers of paint-on die spacer (Belle de St. Claire, Chatsworth, Calif.) were applied to the axial-gingival line angle.

The In-Ceram FPDs were fabricated according to the Vita instructions. This included duplication of the master die in a special plaster, slip cast application of the alumina to the die, carving the FPD to the desired shape and sintering at 1,120 degrees Celsius for the 11-hour procedure. The sintered framework was returned to the master die for verification of fit, adjusted when necessary and then infiltration glass fired with the appropriate shade of glass. The excess infiltration glass was removed and the framework dimensions were measured with a digital micrometer at 28 points and recorded. The veneering porcelain (Vitadur-N, Vita Zahnfabrik) was applied to the desired occlusion, contours and shape.

Delivery and Adjustment Protocol

The provisional crowns were removed, temporary cement debrided and teeth cleaned with a pumice slurry and rubber cup. Proximal contacts were evaluated with Shim Stock marking tape (Micro-O-Reg Shim Stock, Jackson Heights, N.Y.) and adjusted if necessary. The internal adaptation and marginal integrity were evaluated using Fitchecker (GC America, Chicago) and any areas of binding adjusted until the fit was determined to be excellent. Finally, the occlusion and contours were adjusted. If any adjustments were made, the crowns were autoglazed. The dimensions of the FPDs were measured at 28 points. The internal surface of the FPD was aluminum oxide abraded at 40 pounds/inches^2 to debride the surface for cementation. The In-Ceram alumina is of sufficient strength to be unaffected by aluminum oxide abrasion.

Cementation Protocol

The abutment teeth were again cleaned with a pumice slurry and rubber cup. The teeth were then rinsed with water and dried with care being taken not to desiccate them. The FPDs were cemented with a glass ionomer cement (Ketac-Cem Applicap, ESPE). The encapsulated form of glass ionomer prevented measuring and mixing inaccuracies. The capsules were activated and mixed in an amalgam mixing machine, and a thin layer of cement was applied to the internal walls of the retainers. The FPDs were seated with an orangewood stick using a dynamic seating method by having the patient bite down on the stick and wiggling the stick to gain maximum seating of the FPD. A full setting time of 10 minutes was observed leaving the cement undisturbed. The excess set cement was removed with scaling instruments. The occlusion and proximal contacts were reverified.

TABLE 1

Distribution In-Ceram FPDs as defined by location of pontic	
Anterior	21
Premolar	19
Molar	21
Maxillary	31
Mandibular	30

TABLE 2

Failure rate by location of the pontic		
Anterior	0/21	0%
Premolar	2/19	11%
Molar	5/21	24%

TABLE 3

Fractu re location and period to fracture of FPDs						
Patient	Retainer	Fracture	Pontic	Retainer	Period to Fracture	Occlusal-gingival connector Height
KH	28	8	29	30	2 weeks	2.8 mm
RS	18	8	19	20	1 month	3.7 m
JQ*	18	8	19	20	1 month	4.4 mm
HP	2	8	3	4	5 months	3.0 mm
KP	17	8	18	19	12 months	3.4 mm
MB	12	8	13	14	12 months	3.1 mm
ML	18	8	19	20	15 months	3.5 mm

*Bruxer

Recall Evaluations

Measurements were made at baseline, and recall visits were scheduled annually. Evaluation appointments consisted of intraoral photographs, polyvinylsiloxane impressions of the FPD and antagonist teeth and direct clinical measurements. Parameters measured included:

- General oral hygiene;
- Plaque index of tooth and FPD;
- Gingival index of tooth and FPD;
- Pocket depth measurement with pressure-sensitive periodontal probe (Florida Probe);
- Measurement of attached tissue around fixed restorations compared to contralateral teeth;
- Occlusal analysis with determination of:
  - Location of centric contacts,
  - Notation of contacts on veneer porcelain or In-Ceram core material,
  - Occlusal scheme in lateral excursions, and
  - Notation of excursive contacts in veneer or core material;
- Marginal integrity rating (A, B, C);
- Condition of FPD;
- Inquiry as to patient comfort with all teeth and crown; and
- Polyvinylsiloxane impression of antagonist teeth and FPD for measurement of contour changes with MTS Tooth Profiling System.

The primary objective of this article is to explore the longevity factors of all-ceramic FPDs. The details of the other clinical parameters will be presented in other papers.

Results

A total of 61 three-unit In-Ceram FPDs were cemented in 47 subjects. Subjects ranged in age from 19 to 66. **Table 1** shows the distribution In-Ceram FPDs as defined by the location of the pontic. Roughly one-third were anterior, premolar and molar pontic FPDs.

None of subjects experienced postcementation sensitivity with the glass ionomer cementation protocol. None of the abutments needed endodontic therapy during the three-year follow-up.

At the three-year recall point with 61 FPDs placed, seven FPD fractures occurred and one patient with one FPD died. In **Table 2**, the failure rate by location of the pontic is calculated.

Table 3 presents information on where the FPDs fractured, the period to fracture, and the occlusal-gingival connector height at the fracture location. All FPDs fractured through the connector, usually in the more posterior connector. The FPDs failed over a variety of time periods, but after 15 months the FPDs seemed to have stabilized and no more fractures occurred. The mean occlusal-gingival connector height of all the posterior FPDs was 4 mm. **Figure 15** shows an FPD that had been fractured for three weeks when the patient presented. **Figure 16** shows that respecting the soft tissues with the gingival embrasure contours and the opposing cusp contacting on the connector along with the sharp occlusal anatomy limited the occlusal-gingival connector height to 2.7 mm.

One patient, JQ, was a bruxer. This was determined by the presence of wear facets and the results of a history taken from the patient at the initial examination. The occlusal-gingival connector height was 4.4 mm. It was the only failed FPD with a connector height greater than the mean of 4 mm.

Fractographic evaluation of the failed specimens showed that in approximately 70 percent of the cases, the origin of failure was usually at flaws located at the interface of the veneer-core materials on the tissue surface of the connector area.[19]

Discussion

The Vita Company recommends that the In-Ceram System be used only for anterior FPDs. The present clinical study attempted to push the material to its limits by testing the In-Ceram ceramic for posterior FPDs as well. When broken down by location, the failure rate was 0 percent for anterior pontics, 11 percent for premolar pontics and 24 percent for molar pontics. In reviewing the seven failed FPDs, fracture always occurred through the connector. No fractures of the retainers occurred. There was no clear typical period until failure. Several FPDs fractured in the first four weeks of service, some fractured

at five to six months, and some at 12 months. The longest period before failure was 15 months. Fractographic evaluation of the failed specimens showed that in 70 percent of the cases the origin of failure was located at flaws of the veneer-core material interface on the tissue surface of the connector area.[19]

The results of this study were similar to the Coornaert and colleagues[16] study of metal-ceramic restorations in that the majority of failures occurred within the first year after cementation. The early failures were most likely due to technical problems in fabrication of the In-Ceram FPDs, such as inclusion of large flaws.

Hüls'20 clinical data on In-Ceram FPDs had similar results to the authors' study. At three to six years, he recorded no failures of anterior FPDs and a 19 percent failure rate of posterior FPDs.

The authors' results showed that the In-Ceram alumina cannot be reliably used for posterior FPDs. However, if one wanted to use In-Ceram in posterior applications, the results indicate that the veneer porcelain application on the tissue surface of the connector is not necessary and may eliminate the possibility of voids being formed at the veneer core interface. Further, this would allow for increased occlusal-gingival connector height made of the core material. The study did not show evidence of breakdown of the exposed alumina core material.

Attempts to develop other more conventional all-ceramic FPD systems have been frustrating. Claims were made by the Jeneric/Pentron Company that the Optec system had sufficient strength for fabrication of FPDs even when only veneer retainers rather than full crown retainers were used. Christensen and Christensen21 tested 40 FPDs with a variety of retainer designs and at two years found an 80 percent failure rate for posterior FPDs and a 22 percent failure rate even with full crown retainers on anterior FPDs. In the present study, since none of the In-Ceram FPD failures occurred in the retainers, it can be assumed that single crowns made of In-Ceram should have failure rates equal to or better than metal-ceramic crowns.

It is not yet known how many years of evaluation are needed to reliably predict great clinical longevity and sufficient resistance to the adversarial oral fatigue phenomena for an all-ceramic system. However, the 100 percent success rate of anterior In-Ceram FPDs in the present study and in Hüls'20 research is encouraging.

The main purpose of this paper was to present longevity factors for the In-Ceram FPDs.

Future papers will present the results of other clinical parameters.

Conclusions

At the three-year point in this clinical study of In-Ceram alumina three-unit FPDs, the following conclusions can be made:

- Seven out of 61 FPDs failed by fracture through the connector area.
- By location of the pontic, failure rates were 0 percent for anteriors, 11 percent for premolars and 24 percent for molars.
- The results are supportive of the manufacturer's suggested utilization of the In-Ceram system for anterior FPDs.
- Glass ionomer cement can be predictably used to cement In-Ceram FPDs with few clinical side effects.

Acknowledgments

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CDA JOURNAL, VOL 26, Nº3

A Dentist's Lament

Robert E. Horseman, DDS

We are ambivalent in our feelings toward that section of the media devoted to hawking dental hygiene products. We welcome the little asides recommending that people visit their dentist but sometimes deplore the rest of the message. Arguably more acceptable than those commercials for products touted to address a host of women's personal bodily functions and certainly more believable than, say, those for used cars, still, dental ads are like having a rich but very eccentric uncle. He's the one who is apt to embarrass us to death at any time, yet also has the potential to enhance and further our own agenda.

So we tolerate the excessive claims and extravagant promises, accept the free samples and colorful literature. At the same time, we shy away from embracing the blatant commercialism and keep our own counsel.

Take toothpaste, for example. In spite of our personal beliefs and the public pronouncements of the American Dental Association on the matter, toothpaste manufacturers are always on full red alert for any ingredient, no matter how bizarre, to galvanize a gullible public. No matter that the only significant addition to toothpaste in the past 100 years has been fluoride. Fluoride, unfortunately, is as common as dirt and is in everybody's product, so it has little advertising value. The past few years have seen a constant parade of multicolored gels, peroxides, baking sodas and "tooth whitening additives," none of which has any scientific proof of efficacy. The old "4 out of 5 dentists recommend" bit has been done to death, but the packaging of the product is sometimes innovative, accompanied by equally innovative pricing.

You've got plastic tubes that refuse to stay rolled up. There are stand-up pump cartridges, screw-on caps, snap-on caps, simultaneous squirting of two ingredients to be mixed together in your mouth and, of course, The Promises. Ah yes, The Promises. Your tartar is controlled, or at least seriously restrained. Clean, sparkling white teeth and breath like a spring garden are yours for the asking. Likewise, firm, pink, healthy gums and a love life so fervid that suitors have to take a number just to get near you. Fantastico! Just what we had in mind ourselves, with minor reservations.

As dentists, we can but shake our heads in wonder. We know that if your teeth were beige before brushing, they're most likely to be beige after. The toothpaste companies know this, too, but the word "white" carries so much cachet, their judgment gets clouded. They never stop to think that you could do a better job

CDA JOURNAL, VOL 26, Nº3

with a bottle of White-Out from the local stationery store.

Many dentifrice companies also offer their own version of a toothbrush. It's a natural pairing, like selling shoelaces with shoes, tires with wheels, belts with pants. The same advertising people who have been fantasizing about toothpaste can now couple their knowledge of human frailties to the art of retailing toothbrushes. And the public is ready. Not believing that a toothbrush is a toothbrush is a toothbrush, they are eager to embrace any new angle in the handle; tufts on the end, on the side; flat; curved; blue centers; serrated, escalloped; and in fluorescent pink, plum and cherry apple red. It can be battery-powered, solar-powered, or belt-driven from a hamster's exercise wheel. At a substantial discount, they will sell us these brushes by the bulk and send us tons of literature so we can give them away to our patients.

It's a nice symbiotic relationship. And we can't complain; we both have the same goal with a slight variation: They're trying to make a living, and we're trying to prevent the troubles that provide us our living. Hey, if we were all that smart, we'd be lawyers.

The mouthwash people found out this was a heck of a system, and they have done the toothpaste people one better. Capitalizing on the fact that the human mouth is, to put it delicately, a cesspool, they have featured in their TV ads a colorful depiction of the microbial horror that resides there. Every imaginable germ in every histological configuration you can think of is rampant on the screen doing the backstroke, crawl, butterfly and breast in demented patterns and colliding with one another like bumper cars in an amusement park. Suddenly a tsunami of the company's product sluices over the scene, and the bugs are quicker to throw up their cilia and pseudopods and expire than those equally unhygienic bugs in the RAID commercials. You are then encouraged to get on with your life, germ-free for upward of 30 seconds or so.

Sort of hanging around on the advertising fringes are the denture adhesive and cleanser people. The denture cleaning ad people obviously believe that showing real dentures being soaked is pretty gross, so they favor rectangular blocks of what appears to be chalk dunked in their product with stains disappearing as if by magic.

The adhesive folks are even more chaste. They figure they can get their point across, namely that their paste is the equivalent of industrial cement and can attach to pencils and fingers with aggressive ease. Ergo, by the same token, it must follow that their dentures, discreetly hidden from the viewer, must stick to the gums with gratifying tenacity. Would that the company could turn its attention to a solvent for this stuff, which defies Brillo pads and fire hoses to dislodge it from both denture and gums.

It must drive the ad agencies up the wall when leading dental authorities go public with the opinion that, given a choice of either a toothbrush or floss to maintain oral health, floss would win hands down. Furthermore, it's the brush that does the trick, not the paste; and even with the brush, it's the amount of time in use rather than the design that's important.

How long have we been saying that? Not long enough apparently.