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General Discussion

BARON: I would like to comment briefly on the diagnostic criteria for incipient lesions. Certainly, I would agree that the diagnosis of incipient lesions is important, but urge some caution in interpreting white spots as incipient or weak caries lesions. Obviously, the white spots that we can diagnose are located on those surfaces that we can visualize. In contrast to approximal surfaces and pits and fissures, these smooth surfaces where the white spots are seen result only occasionally in frank cavitation. Second, white spots are caused by conditions other than plaque-induced demineralization — for example, fluorosis, hypoplasia, and demineralization induced by acid chemicals. Third, if white spots were a signal of a potentially dangerous situation, *i.e.*, one leading to cavitation, then it would be useful to study a group which produces a high incidence of white spots. One should expect a correspondingly high incidence of caries. Such a group does exist — namely, patients undergoing orthodontic treatment. Demineralized enamel which appears as white spots is commonly found in such patients. From a recent literature search and review on this subject, there is no evidence to suggest that the incidence of caries in orthodontic patients is any greater than in a non-treated population. Therefore, I would urge caution on the assumption that these white spots should be interpreted as a pre-caries lesion and merely challenge their inclusion in any statistical analysis of caries data. I think it is potentially misleading.

STOOKEY: I think one of the changes that have occurred since the last conference is the change in design, not to be able to use negative controls in many kinds of situations. This then changes the design of the study where you are using a positive control to show equivalence, interpreted to mean that you have a significant treatment effect.

DONNELLY: I should like to point out that there is a less-defined period when first exposure at risk occurs with root caries than with coronal caries. Second, there are some morphological differences between these two classifications of caries that need to be mentioned. The DMF system provides the opportunity to get some estimation of individual attack rates for each separate coronal attack. The crowns of the teeth have pits and fissures with discrete lesions so that discrete restorations can be found; there are proximal contact points with lesions associated with them. The root area is a more likely place for smooth surface caries than the crown. A tooth like the upper first molar can have two roots exposed, so we have the problem of recording one or two caries attacks. The lesions readily extend to additional surfaces, making it an even greater problem with root caries than it is with the coronal surfaces. I think in root caries that extension into the approximal areas is a problem of recording as well as of restoration. Different methods of access are used for proximal surfaces and root caries, which is also an important consideration. The susceptibility by tooth and by surface also appears to be quite different from that of coronal caries, so that Grainger's categories won't apply to root surface caries. The presence of calculus and heavy plaque and debris may interfere with examination. Accessibility of populations for study can be more difficult with root caries.

VONGRIES: At the first session, Professor Holloway asked a question concerning the ethical aspects of dental radiography in caries clinical trials. The response by one of the panelists conveyed the impression that it is an acceptable procedure and indeed that it provides a benefit —

copies of the radiographs are sent to private dentists.

The record of this conference should, I believe, include another viewpoint, namely, that it is unethical to obtain radiographs during the course of a caries clinical trial when they are not necessary for the dental treatment of the individual child.

There can be no disagreement that X-radiation is harmful and that radiography should be limited to the minimum necessary for the medical and dental care of the individual. While bite-wing films should involve less exposure than many other diagnostic radiographic procedures, it is questionable whether an investigator has the right to decide that the hazards can be ignored. The risks of all procedures in clinical trials have to be weighed carefully.

Radiographs in caries trials are obtained to generate data, although some films incidentally identify pathology that should be treated. In some cases, recent radiographs were obtained in a private dentist's office. Some of the children have normal X-rays throughout the study. Sending copies of radiographs performed as part of the trial to private dentists doesn't justify the procedure. Most of the X-rays are unnecessary to the dental care of the subjects. It would, of course, be unconscionable to obtain the copies by taking repeat films.

The obvious argument is that the information derived from the radiographs is necessary, but this can never supersede the ethical considerations. The "need for the data" has motivated a number of investigators to behave unethically, and the extremes led to codes of ethics such as that developed at Helsinki. Personally, I don't see much difference between being a little unethical or very unethical. Fortunately, it appears to be possible to conduct caries trials without using radiographs.*

NAYLOR: One need remember that root caries is not necessarily a disease of the aged. We see root caries in young people who have undergone periodontal surgery and in people who have recession in their early years for various reasons, maybe misuse of toothbrushing, as well as those people who have undergone radiation therapy. It is extremely important that we have an index, because without an index we cannot make an adequate evaluation, and without an adequate evaluation, treatment is empirical. It is extremely easy to identify and to assess a lesion which will appear on a facial surface, but it is the lesion which is proximal which then causes the clinical problem, the lesion which appears beneath a gold inlay or an amalgam restoration.

One quick word on Janet Brunelle's paper, which is the most timely reminder of something we have been reminded of many, many times: Computers can save us an awful lot of time, but they can also waste an awful lot of time. I am reminded of people who tell me how busy they are, and I go down there and find them playing computer games.

HOROWITZ: Just for the record, I'd like to state that there is sort of an *a priori* assumption that root caries is going to become a major problem in the future. I am not saying that it is not. I am saying that we really don't know

*Ed. note: The role of radiographs in caries clinical trials was not a topic on the program of this Conference. The reader is referred to the proceedings of the following conference which discussed this subject: "Ethical and Legal Considerations in Dental Caries Research Involving Human Subjects", Joanna Jenny, Ed., *J Dent Res* 59 (Special Issue C), 1980.

what the extent of root caries will be in the future. We don't know what it is now, really. The factors that would lead to a conclusion that there will be a bigger problem — *i.e.*, an aging population, more people retaining teeth — may be counteracted by the greater effects of fluoride from more sources. That may counteract this phenomenon. Stamm and Banting showed 50% less root surface caries in a fluoridated community, and as more people live in fluoridated communities or use other fluoride modalities, or use other methods of prevention, we may not experience the upsurge that is anticipated. I have a little problem with your suggestion, Ralph (Katz), that where there is no area of gross cavitation, and if there is no tactile evidence of decay, that we use staining as a criterion for decay. With agents like stannous fluoride, chlorhexidine, or any similar agent, you might reach the wrong conclusion if you relied solely on visual criteria on the root surface for dental caries. Finally, I'd like to comment on whether or not to call a root surface sound when it is completely covered by calculus. I would be more in favor of calling those surfaces "unreadable". We have a precedent for unreadable categories in coronal caries, where we exclude orthodontic and extracted teeth and fractures. I would rather exclude from a decision what is underneath calculus.

BOHANNAN: As an ex-periodontist, I question the general opinion of people that just because you retain teeth longer in the future there is going to be more periodontal disease. I am not at all certain that that assumption is one that we can accept, if the efforts being put into caries research are transferred, one of these days, into periodontal research. I had some concern with Dr. Katz' definition of surfaces at risk based solely on recession. We are all aware of much gingival recession caused by toothbrush abrasion. Some of these surfaces are polished, shiny, with no plaque at all. According to your criteria, I would have difficulty deciding whether these teeth would be at risk in your category or not, based solely on recession. Many of these surfaces are filled, and to assume that they have been filled because of caries is, I think, questionable. Some fillings are placed in abraded, non-carious surfaces because of esthetic considerations or cervical sensitivity unrelated to root caries.

SCHEININ: It seems that the earliest lesion as defined by Dr. Katz would lead us into the same problem as with the white spot — staining could be recorded as root caries.

CASH: Also one quick question for Kwo Hwa Lu: I assume, in order to do calculations, you have to input parameter values. I wonder, have you done simulations against actual data, and if so, how closely can you predict what actually occurred?

GRAVES: Just a comment related to the pro's and con's of taking radiographs in either clinical trials or demonstrations: We just completed this national preventive dentistry demonstration project in which we had two cohorts, a young cohort and an adolescent cohort. We were testing a number of preventive regimes, including sealants and fluoride. They have different effectiveness depending on the surfaces under study. We took only one set of bite-wings at baseline and one set of bite-wings four years later. If it had not been for the additive effects by looking at the proximal surfaces visible on X-ray examinations for the adolescent cohort, we might have come to the wrong conclusions about mouthrinses and tablets in the mouth fluoride in that cohort. We were able to demonstrate a significant advantage of the use of fluoride mouthrinses and tablets that we would not have been able to conclude based on clinical findings only. So I think we need

to consider the ages of the populations under study, the purpose of a particular project that we are conducting, and not necessarily come to broad conclusions that radiographs would not be necessary.

LU: I'd like to say something about radiographs. I'm sure a radiograph is exposing the living tissue to ionization by machines, which is harmful. What I am saying is that everything is harmful. Sunshine is harmful. Living in a brick building is less harmful than living in a wooden building. The risk becomes acceptable when the probability of getting hurt is removed. There are these "zero riskers" who don't want to take any risk; any risk is too great. There is only one way to rid yourself of risk, or protect yourself from all risks from now and forever, and that's to kill yourself immediately.

VOLPE: Or use your simulated model. Then you can take X-rays or not take X-rays.

LU: In answer to Dr. Cash's question, I did use life tables as much as possible, *i.e.*, the risks of different surfaces. I would have been glad to show that, but I had a time limit.

VOLPE: Thank you. I would like some of the other agencies to be thinking about the issue of X-rays, because we can talk perpetually about what we want, but sooner or later the clinicians have to make a judgment. It would help me and a lot of other people. I cannot walk away from the subject.

MARTHALER: As to the study of incipient lesions, that's a very fruitful area of research. I readily admit that using our methods of assessing the presence on the various tooth surfaces has not been as reliable as we wanted, but that does not mean that there is nothing interesting about them. As to X-ray, I would say that that is in some way the matter of personal responsibility. I would get very angry if a politician tells me, because of political issues, not to take X-rays because radioactivity has been increasing in the last four decades. I think the politician is not the one who should give or take responsibility away from me for a thing I think is necessary in certain circumstances.

HOLLOWAY: As a researcher, I cannot say that I *have* to use a potentially dangerous procedure. What I have to do as a researcher is to use my ingenuity to find some other way to get around the use of routine radiographs. I think that's what we have to get ourselves to do.

MANDEL: I am not going to get involved in this X-rated discussion, but I think that the last point is a very meaningful one. We are almost prisoners of styles of conducting studies — the choice of population, the location of the population, and the techniques that we use for diagnosis. I would support the plea for at least bringing us to the middle of the 20th century in diagnostic technology. Periodontists are beginning to do this with such things as pressure probes, and it is clearly something we should be doing in caries trials. For the purpose of the record, I would like to point out that we do have at risk an adult population that did not have the benefit of multiple use of fluorides. They represent the major age group in our population who appeared to be at very substantial risk for secondary or recurrent caries and also potentially for root caries. I would project that we would want to be involved in the development of preventive procedures for these people, and therefore, we must consider the possibility of conducting such trials, as difficult as they are.

CHILTON: I would like to make the point that the root caries index, while extremely important in determining levels in different populations in epidemiological studies, under-enumerates the frequency of the lesion, because radiographs are not used. There is another type of root

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caries which occurs essentially approxmally, below the level of the gingiva, in the area of the gingival sulcus. This can only be observed in the earlier stages, before it reaches the pulp, by either very careful probing or by radiographic examination. This was pointed out when we obtained the first NIH contract to investigate the occurrence of root caries about 15 years ago. The index which Ralph Katz has developed is excellent for epidemiological purposes, but we must remember that it does not fully enumerate the lesion.

I would like to point out that the dental profession is indeed much more careful about protecting patients from ionizing radiation than, unfortunately, are our medical colleagues. Radiologists are often much more interested in documenting things than in the protection of the patient. Some institutions re-take CAT scans because they have later generation equipment, and many of us have had the experience of radiographs having to be taken anew for the same problem at each hospital. I would hope that the use of X-rays and the care which Alex so carefully pointed out are also heeded by our medical colleagues.

STAMM: I would like to point up one element in Ralph Katz' otherwise excellent presentation that I didn't quite agree with.

In his paper, where he discusses surfaces at risk, you will notice that when the CEJ is not visible, the surface does not come at risk. We started with that problem, and I have to feel that, in elderly people with approximal restorations, the CEJ is obliterated, and that becomes a newly conservative criterion. That might be one area we are amending. We under-reported initially in that particular area to our own detriment, I think. Another area in the index that you might develop further is reliance on the staining criteria. You will see how often middle-aged and elderly populations are exposed to it. It is clearly staining, but it is hard. I am not quite comfortable with using the word "or" where Dr. Katz uses it. I think softness should be retained in the evaluation of the lesion.

The third area where a little comment is needed is, what do you do with the cervical restoration in regard to the CEJ? Is that a feeling that exists because of the enamel caries in a classified area, or is that a true feeling that's there because of a root lesion that was mentioned some time before? You have to give consideration to that.

ZIMMERMAN: Since we are ending this discussion alphabetically, I would like to say a few words on behalf

of the cancer trial that is getting a lot of beating here. In cancer we have phases one, two, and three toxicity for medication, and phase three for the trial. If you stop at phase two, a two-tailed test, and you see people dying, I only do a one-tailed test, which is the only meaningful one. If we are looking for a drug to induce toxicity that performs as well as the standard procedure, I would do the type of negative test to which Neal alluded. If people say they like a three-tailed test because they are more conservative, they are saying they would like a smaller alpha value or higher critical level. Why don't they do it that way, and stop the one-tailed test?

VOLPE: Thank you very much. With those comments, I bring this session to a close. I'd like to thank the audience and particularly our speakers. Neal, that's it.

SCHROTENBOER: I would like to make a few comments all in the same general area. That's one of appreciation and thanks. First of all, I'd like to express my appreciation and thanks to all of you for attending, for sharing your expertise with each other, and also for providing the expertise to the much larger audience in the future when these proceedings are published. Second, I would like to extend particular thanks to those who prepared and presented papers and those who discussed the papers — that includes practically all of you. That's the second thanks to all of you.

Third, I would like to express my thanks to The Procter & Gamble Company and Colgate-Palmolive Company for their receptions. I would now like to turn the meeting over to Neal for some brief remarks.

CHILTON: Thank you, Gordon. Gordon has thanked everybody, and I want to thank Gordon. When he undertook to run this meeting for the American Dental Association, he did not have the duties of the Assistant Executive Director for Scientific Affairs. At that time he only wore two hats. Now he has many, many hats, and sometimes I think he wishes he had as many heads and hands to go with those hats! We thank him very much. Personally, I would like to thank everybody here very, very much for all of your efforts to make what we think has been a very successful conference. I look forward to seeing all of you again, perhaps at the next caries conference or the next periodontal conference. I wish you all well and God-speed back home.