Session III: Potential Design Improvements —Arje Scheinin, Chairman

Improvement of Diagnostic Methods in Clinical Caries Trials

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Introduction.

Most earlier conferences on clinical trials were carried out with the background of high caries activity. In children, average caries incidence figures tended to fall in the range of two to four new decayed surfaces *per* year. In addition, if fillings were placed, they were often not done immediately after the cavity had formed. These general conditions were favorable for the conduct of clinical caries trials.

In recent years, the situation has changed dramatically. In the majority of the countries in which clinical trials have traditionally been conducted, caries prevalence is declining. At the first "International Conference on Declining Prevalence of Dental Caries", some consequences for clinical caries trials were discussed (Alman, 1982; König, 1982).

The purpose of this paper is to discuss new methods of detecting or diagnosing caries lesions. Bearing in mind the changing conditions as described above, we have focussed our main interest on whether new methods will provide remedies that overcome the new difficulties met with in clinical caries trials.

Some comments on traditional methods of diagnosing caries and on partial recording.

From a *Technical Report* adopted by the FDI (1982), we quote: "Dental caries proceeds from an initial lesion that cannot be diagnosed clinically to an advanced lesion which can be recognized by the most cursory examination. Somewhere between those two extremes the lesion becomes clinically or radiographically detectable". This statement expresses what is evident from the entire report: Examinations are tacitly assumed to be done using mirrors, explorers, and radiographs. Other recommended conditions are a constant source of artificial light, and prior cleaning and drying of teeth.

Even with simple instruments such as a mirror and a probe, a lesion may be defined in different ways. In the earliest reports using DMF counts explicitly, teeth were considered carious when they showed "actual, although frequently small, cavities" (Klein *et al.*, 1938). In the other basic report using the DMF system, the examination "included recording the slightest degree of caries . . . . Pits and fissures in which the explorer caught but which on careful examination were definitely not carious were not counted as caries" (Klein and Palmer, 1937). This type of examination and definition was the primary criterion for the "Anglo-American" procedure of diagnosing caries (Howat and Holloway, 1977). Conversely, these authors termed "European systems" those which are based primarily on detailed visual examination.

A comparison of the two approaches, limited to irreversible lesions requiring restorative treatment, suggested "that an experimental clinical trial will be twice as efficient if the European diagnostic system is used rather than the Anglo-American" (Howat and Holloway, 1977). This conclusion was based on a sample of 99 children who took part in a two-year clinical trial of a caries-preventive agent. Average DMF surface increments ranged from 1.5 to 1.0. The two methods resulted in similar percent reductions (from 33 to 39%).

The "European" system and several of the modern methods of detecting incipient lesions are or may be more time-consuming than the "Anglo-American" system. This may be compensated for by partial recording systems. Their usefulness in incidence studies has been demonstrated by Rugg-Gunn *et al.* (1975). A later paper showed that some systems were more robust than others when applied to a variety of epidemiological data (Marthaler and Steiner, 1981). One partial recording system is used extensively in Switzerland (Marthaler, 1982), France (Cahen *et al.*, 1982), and The Netherlands (Truin *et al.*, 1981). Partial recording, omitting the lingual surfaces, may be indicated when photographic recording is used in conjunction with modern methods of detecting smooth surface caries (under ultraviolet or visible laser light, as explained in the next section). Omission of the lingual surfaces results in a fairly constant loss of 8% of the total DFS experience (Marthaler and Steiner, 1981).

Visual and radiographic examinations permit the definition of several stages or grades of caries lesions. To date, most clinical trials presented findings using one caries grade only.

New methods of detecting caries.

Improved or new diagnostic methods to detect incipient caries may serve the following purposes:

(a) better reproducibility than traditional methods. In view of the large individual variation, the reproducibility (or repeatability) of the traditional methods was considered acceptable by the majority of workers. However, in light of the decreasing number of caries lesions now often encountered, better repeatability is becoming more important. In addition, training and calibration of examiners may be facilitated.

(b) reliable detection of incipient lesions which have not yet developed into cavities. Progress in this field would diminish the number of children showing no increment on the traditional level of recording dental caries.

(c) creation of a permanent record of the pathology at a given time point. On permanent records, direct comparisons of the status at different periods can be made. Blind assessments of all kinds are facilitated. In addition, independent assessment by other examiners is possible. Radiographs provide an excellent example of a permanent record.

Attempts to improve or to develop new methods of detecting caries lesions have been numerous. Summaries covering methods reported up to 1977 have been presented by Bibby and Shern (1978) and Rawls and Owen (1978).

The use of *ultraviolet light* is probably the oldest method suggested for diagnosing dental caries. It has hardly been used, in spite of its theoretical advantages (Alfano and Yao, 1981). Kleinberg *et al.* (1978) presented a photographic method making exposures to ultraviolet light unnecessary. In addition to its applications in clinical caries increment studies, the authors suggest that this method could be useful in the dental practice: Ultraviolet detection could serve as an early warning of future serious damage and alleviate the need for caries susceptibility tests.

Change in *electrical resistance* as an indicator of fissure caries was already proposed in 1951 (Pincus). The necessary scientific background and refined equipment, however, have only recently been made available. Markedly improved sensitivity and specificity were reported when compared with diagnosis using an explorer (White *et al.*, 1978). Resistance measurements appear to record small surface changes which an explorer fails to detect. In a two-year follow-up study comparing these two methods, electrical resistance measurements proved to be superior predictors of later cavity development than was the explorer (White *et al.*, 1981).

Fluorescent dye uptake is another method which has been suggested for the early detection of caries (Rawls and Owen, 1978). In areas of increased porosity, associated with demineralization, dye uptake was greatly increased. Preliminary work in our laboratories showed that this method was very sensitive and useful regarding penetration along filling margins and enamel cracks. However, with respect to caries lesions, the method was difficult to use. Slight procedural variations, often inevitable under field conditions, can result in widely different degrees of dye uptake. It is at present unknown whether this method can be standardized sufficiently for field trials.

Ultrasonics may detect changes in the physical properties of hard tissues, as demonstrated by Lees (1978). It is suited for presumed lesions under a macroscopically sound enamel surface. The author is not aware of any subsequent work with this technique.

Peltola and Wolf (1981) have reviewed the use of *fibre optic transillumination* for detection of approximal caries. When using radiographs and transillumination (Table 1), Mitropoulos found similar numbers of approximal lesions with dentin involvement.

A contingency table (Table 2) provides interesting information. Nineteen surfaces were diagnosed as carious in either type of examination. On 11 surfaces (4 and 7), discrepant findings were obtained. Among 133 surfaces unreadable on radiographs, five were diagnosed as carious using compressed air and the fibre optic light for transillumination. Reliability co-efficients in a study involving 250 children were 0.953 (initial exam, age 12-13 years), 0.964 (final examinations 26 months later), and 0.925 for the incremental data of the 26-month-period.

Further analysis of transillumination findings warranted the conclusion that "the incremental reliability of this system is comparable with radiographic examination, and the severe disadvantage of irradiating subjects during a clinical trial and the problem of overlapping surfaces are overcome".

Bjelkhagen *et al.* (1982) studied early detection of enamel caries by *luminescence* excited by *visible laser light.* Incipient enamel lesions, hardly visible as white spots, appear as dark areas. On the other hand, dentinal caries was barely perceptible. The authors considered this method to be useful with respect to smooth surface and fissure caries.

Laser luminescence has not as yet been studied with respect to approximal surfaces. If applicable, it would result in detection of caries at an earlier stage than transillumination, which depends mainly on dentinal changes. Laser luminescence may prove to be more sensitive than ordinary radiographic examination.

Some comments regarding new and traditional methods of examination.

Table 3 lists the new methods and, in the lower part, the traditional ones. As far as may be inferred from published reports, none of the new methods appears as universally useful as the traditional "clinical" examination with mirror and probe. This type of examination is thought to continue to play an important role. The new methods may often be a supplement rather than a substitute.

There is a growing tendency among investigators to regard radiographic examination of approximal surfaces as unjustified. However, there are useful and informative scientific reports based uniquely on radiographs (*e.g.*, Axelsson and Lindhe, 1981). Studies on the ethical aspect of taking radiographs in clinical caries (and periodontal) trials should be made in the context of radiographs as used in pedodontia, orthodontics, and periodontics, and in radiation exposure other than of dental or medical origin.

In addition, there is another aspect to be considered. New types of clinical caries studies may meet with mounting interest. In 1970, von der Fehr *et al.* published results of a clinical caries study with an intensive cariogenic challenge, obtained by nine daily rinses with sucrose solutions. Evaluation was made by grading white spot lesions already visible after 23 days of experimentation. This type of re-

TABLE 1
AVERAGE NUMBER OF DECAYED APPROXIMAL SURFACES IN 25 CHILDREN. (ENAMEL RADIOLUCENCIES WERE NOT CONSIDERED ON THE RADIOGRAPHS.)

	Clinical Examination Only	Clinical Exam. Combined with Radiographs	Clinical Exam. Combined with Transillumination
All Approximal Surfaces	1.36	1.64	1.68
Posterior Approximal Surfaces	0.76	1.16	1.04

Adapted from Table 7.1 of Mitropoulos (1982).

TABLE 2
CONTINGENCY TABLE OF APPROXIMAL SURFACES DIAGNOSED BY MEANS OF RADIOGRAPHS AND TRANSILLUMINATION

Result of Transillumination Examination	Result of Radiographic Examination		
	Sound	Carious	Unreadable
Sound	396	7	128
Carious	4	19	5

Adapted from Table 7.2 of Mitropoulos (1982).

search was apparently not followed up. The future, however, may bring about renewed interest along these lines for two reasons: better assessment of incipient caries by new methods such as those listed in Table 3, and recent progress regarding remineralization of early lesions (see, *e.g.,* Amjad *et al.,* 1982; Featherstone *et al.,* 1982; ten Cate and Duijsters, 1982).

How valid are incipient lesions for assessing inhibition of carious destruction?

Six years have elapsed since Bibby and Shern (1978) summarized a discussion on incipient lesions: "A common criticism raised by many speakers was that few investigators had attempted to determine whether the technics employed are detecting early carious lesions. It was also suggested that some of the lesions examined were enamel defects unrelated to dental caries. It was agreed that one or two approaches, particularly that detecting changes in enamel resistance, held some promise and that a longitudinal study being carried out should help to determine the validity of this approach."

It was generally assumed that radiolucencies limited within the enamel were mandatory precursors of dentinal radiolucencies. The gradual penetration of enamel radiolucencies through enamel has been studied by several authors (*e.g.,* Marthaler and Wiesner, 1973; Berman and Slack, 1973; Gröndahl *et al.,* 1977). Most epidemiologists would, on the basis of the results of these studies, agree that inhibiting the change from sound to radiolucent enamel would lead to reduced numbers of dentinal radiolucencies. Granath *et al.* (1980) showed that the progression of enamel radiolucencies was slower in children with low caries activity as compared with those with high caries activity.

New data on the progression of incipient lesions to cavities are available from 43 control and 82 test subjects initially examined in 1964-65 and again in 1976 (Saxer and Marthaler, 1982). The 43 control subjects had never taken part in organized preventive programs and developed an average of 0.41 new DF surfaces per year. The 82 test subjects had lived in a community with a school-based preventive program which had been in operation since 1963. Their average annual caries increment, in contrast, was only 0.23 DF surfaces. The pertinent data of this study are listed in Table 4. Bear in mind that, due to the initial age of the subjects, most sites studied over the nine-year period were located on the first molars.

The radiographic findings correspond with the results of Granath *et al.* (1980). Under the influence of the preventive program, larger proportions of initially sound surfaces remained sound or progressed only to incipient lesions. In the control children, only 13% of the enamel radiolucencies detected at the initial examinations were still limited to the enamel. In contrast, this percentage was twice as high in the test children in the preventive program (27%).

Similar observations were made in the pit and fissure sites. Progressions from sound to decayed and from incipient (discolored fissures) to decayed sites were clearly re-

TABLE 3
TENTATIVE USEFULNESS OF NEW AND TRADITIONAL METHODS OF DETECTING CORONAL CARIES

	Possible Usefulness with Respect to Assessing Caries . . .		
	of Pits and Fissures	of Approximal Surfaces	of Free Smooth Surfaces
Ultraviolet	?	?	+
Laser Luminescence	+	?	+
Fibre Optic Transillumination	?	+	?
Fluorescent Dye Uptake	?	+	+
Ultrasonics	?	?	+
Electric Resistance	+	–	?
Visual	+	+	+
Tactile	+	+	+
Radiographs	–	+	–

+ = Usefulness established or demonstrated.
? = Usefulness not yet demonstrated.
– = Usefulness unlikely.

TABLE 4
INITIAL STATE (1964-65) OF CARIES PREDILECTION SITES OF 7-TO-10-YEAR-OLD SUBJECTS AND FINAL STATE (1976)

Initial State of Sites	No Prevention (N = 43)				Prevention (N = 82)			
	N of Sites	State in 1976			N of Sites	State in 1976		
		Sound	Inc.	DMF		Sound	Inc.	DMF
Approximal Sites on Radiographs								
Sound	118	11%	14%	75%	274	20%	40%	40%
Incipient Lesion	67	5%	13%	82%	88	14%	27%	59%
Fissures and Pits								
Sound	62	10%	32%	58%	174	26%	37%	37%
Incipient	72	3%	22%	75%	96	1%	45%	54%
Smooth Surfaces of Molars								
Sound	97	38%	36%	26%	281	63%	33%	4%
Incipient Lesion	66	27%	49%	24%	37	43%	51%	6%

Subjects with prevention (N = 82) had profited up to age 15 from a school-based preventive program consisting essentially of six toothbrushing exercises *per* year, coupled with fluoride application and dietary information. Incipient lesions on radiographs: Radiolucencies limited to the enamel. Incipient lesions in fissures and pits: brown or dark discoloration. Incipient lesions on free smooth surfaces of molars: white spots. Data from Saxer and Marthaler (1982)

duced by the preventive program. This implies that discolored fissures were precursors of cavities, just as enamel radiolucencies are precursors of dentinal radiolucencies. Pathogenically, the precursor role of discolored fissures is less stringent than that of enamel radiolucencies penetrating later into dentin.

Table 4 shows that white spots on free smooth surfaces may also be regarded as precursors of cavities. Under the effect of the school-based preventive program, only two of 37 sites progressed to the DF state.

This study also included an older group (initial age, 11 to 16 years), consisting of 35 control subjects and 54 subjects in the preventive program. The findings were similar to those described above (Saxer and Marthaler, 1982).

These results confirm previous conclusions (Marthaler, 1978) regarding the potential usefulness of the technics of detecting incipient lesions. This may be important especially with respect to examination using ultraviolet and visible laser light. Research on how to combine findings obtained with different methods may be performed using the approach outlined by Howat (1981).

Incipient lesions and interference of dental treatment.

F-components of the DF counts have been low in many countries up to recent times. Accordingly, interference as a result of restorative treatment was not a matter of great concern to dental epidemiologists. Adequate treatment of caries, however, was also encountered in earlier years. In Scandinavian countries, few unfilled cavities were recorded by the 1950's or '60's. As an example, Koch (1967) used the F increment as a measure of caries increment to study the caries-inhibiting effects of various schemes of topical F applications.

In the city of Zürich, an average DF increment of 23.8 was observed in a control group (99 children) studied over a period of seven years. The FS increment was as high as 21.2. In the fluoride group, the DFS increment was 16.1, and the FS increment 14.9 (Marthaler, 1968). This was due to treatment at the school dental clinics, with approximately 40 dentists treating 30,000 to 35,000 children. Examinations carried out in 1977-1979 resulted in DS averages below 1.0.

DMF data obtained in 14-year-old children in the Canton of Zürich (Marthaler, 1981, completed by Marthaler *et al.*, 1982) showed 6.4 DS as part of a DFS of 22.7 in 1963-64. By 1967-68, the DS had decreased to 2.9 and gradually fell to 2.03 by 1979-80, the DFS being 7.2 (Table 5). Within the DS of 2.03, dentinal radiolucencies accounted for 1.33 DS. Similar improved dental care has been reported by Ripa *et al.* (1983) in the US, and there are many similar reports from countries with declining prevalence of caries.

It is obvious that dentists' interference with incipient lesions is less than in the case of cavities which almost always need to be filled. The study of incipient lesions by modern methods thus appears to be rewarding from this point of view as well.

TABLE 5
AVERAGE NUMBER PER CHILD (N=715) OF INCIPIENT LESIONS AND DF SITES AT AGE 14, RECORDED 1979-80 IN 16 SAMPLE COMMUNITIES IN THE CANTON OF ZÜRICH, IN CHILDREN AGED 10 YEARS AND 14 YEARS

	Total Number of Sites	Sites* with Incipient Lesions Age 10	Incipient Lesions Age 14	Decay or Filling Age 10	Decay or Filling Age 14
Radiolucent Areas in the Buccal Segment	24	2.2	8.3	0.5	2.0
Fissures and Pits of Molars and Pre-molars	22	2.6	5.7	1.9	4.9
Free Smooth Surfaces of Molars	16	0.7	2.0	0.1	0.1
DFS**	92	–	–	2.6	7.2

*Sites correspond to tooth surfaces except for the buccal surfaces of the lower molars and the lingual surfaces of upper molars, where caries of the pit or groove is recorded separately from smooth surface caries (examination according to Marthaler, 1966; for grading of lesions see also Marthaler, 1978).

**Partial recording system retaining on average 93.6% of the total DFS experience (Marthaler and Steiner, 1981).

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Improvement of Diagnostic Methods in Clinical Caries Trials: Discussion of Dr. Marthaler's Presentation

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Dr. Marthaler has presented an excellent review of the recent improvement in diagnostic methods used in clinical caries trials. My discussion will be just that! I shall not add to his fine review of the literature but merely emphasize certain points which he has made in his presentation.

As Dr. Marthaler has noted, there are several new problems confronting investigators conducting clinical caries trials in 1983. These include a declining prevalence of dental caries, earlier restorative intervention by community dentists, the inability to use a placebo dentifrice in clinical trials, and the general avoidance of "routine" radiographs in clinical trials.

It is difficult for the investigator to control these new variables. Certainly the declining prevalence of dental caries is laudable. In some respects, it is a direct result of the earlier trials of fluoride dentifrices and other preventive dentistry aids. As patients have been seeking better and earlier dental care, our colleagues in clinical practice have been restoring caries lesions at very early stages of development. Lesions that at one time were difficult for the investigator to detect are now readily perceptible to community dentists and therefore can be readily restored. This restoration is easily visible by the clinical examiner at a subsequent year.

Ethical considerations and the general public acceptance of fluoride dentifrices prevent the conscientious investigator from using a placebo dentifrice, at least in studies with caries-prone children. The declining caries prevalence and the greater awareness of hazards of ionizing radiation suggest that it is not appropriate to take radiographs on a