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Factors Involved in Validity Measurements of Diagnostic Tests for Approximal Caries – A Meta-Analysis

Key Words
Approximal caries
Diagnosis
Validity
Visual inspection
Radiography
Fibre-optic transillumination

Abstract
In this study, a meta-analysis was performed on published validity parameters of visual inspection, radiographic examination and visual inspection upon fibre-optic transillumination (FOTI) in approximal caries diagnosis. It was the objective to investigate the influence of the diagnostic test, the study design and the validation method on reported validity. Sensitivities and specificities reported in the literature were transformed into D_z values, representing the performance of a diagnostic method above chance, or of the observer using it, in a single parameter. D_z values were neither statistically significantly different between visual inspection, radiographic examination and FOTI nor between 'weak' and 'strong' validation methods ($p>0.05$). D_z values obtained from in vivo studies were significantly different from those obtained from in vitro studies ($p<0.05$), indicating that study design had a significant impact on the measurement of the validity of the evaluated test for approximal caries diagnosis.

The prevalence of dental caries has decreased considerably during the past three decades in most Western populations [Glass, 1981; von der Fehr, 1982; Marthaler, 1990; Truin et al., 1991, 1993]. For the purpose of caries diagnosis in individuals with a high caries experience, the use of visual inspection, occasionally aided by bite-wing radiography, has long been considered appropriate. With the decline in caries prevalence it became, however, evident that these diagnostic methods performed inadequately. The impact of caries prevalence on the performance of diagnostic tests like visual inspection and radiographic examination is considerable. Wenzel et al. [1993] and Verdonschot et al. [1993c] demonstrated that the probability of true-positive test results is outweighed by the probability of a false-positive test result at a caries prevalence of 10–20%, i.e. when only 1 or 2 out of 10 surfaces are carious. The need for more sophisticated caries-diagnostic techniques has been acknowledged and much research has already been conducted to design, improve and validate new diagnostic methods.

As a result, many studies aimed at evaluating improved or new diagnostic techniques for approximal caries diagnosis have been published. Some of these studies were conducted under in vitro, others under in vivo circumstances. In these studies, a variety of validating methods have been employed to establish the 'true state of disease', whereas the cut-off between sound and diseased cases (teeth, surfaces) was placed between different stages of lesion progression. Although the use of receiver operating characteristic (ROC) analysis, plotting sensitivity as a function of (I-specificity), has been advocated to evaluate the validity of a diagnostic

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test [Verdonschot et al., 1993a, b], many studies published in the past 13 years reported on the validity in terms of sensitivity and specificity, which in fact respresent only one point on a ROC curve. Sensitivity reflects the number of true-positive cases relative to the total number of actually decayed cases, whereas specificity reflects the number of true-negative cases relative to the total number of actual negative cases. In discussion sections of such publications, these measures of accuracy were often compared to those from other studies to obtain an insight into the relative performance of the diagnostic tests under study. It is evident from the variety of materials and methods applied in diagnostic studies focused on approximal caries diagnosis that the published validity parameters are difficult to compare. In this study, a new parameter is introduced to facilitate a comparison of sensitivity and specificity values from different studies. This parameter was subsequently used in a meta-analysis performed on published data on the performance of visual inspection, radiographic examination and visual inspection upon fibre-optic transillumination (FOTI) in approximal caries diagnosis. It was the objective of this study to investigate the influence of the diagnostic test, the study design and the validation method on the reported validity.

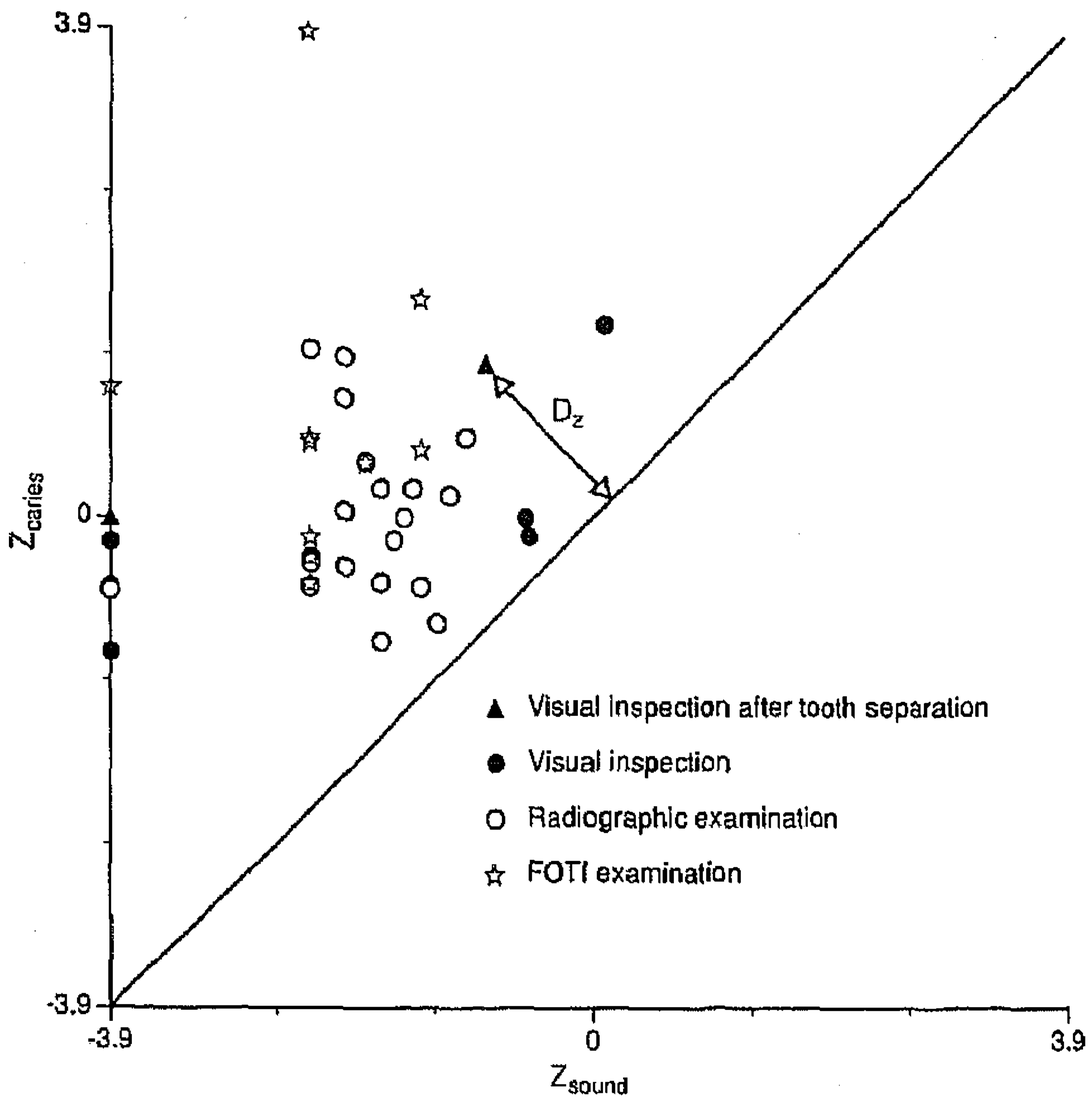

Fig. 1. Normal-deviate values of sensitivity plotted against normal-deviate values of 1-specificity of visual inspection (with and without tooth separation), radiographic examination and visual inspection upon FOTI.

Materials and Methods

A literature search was conducted to find publications which appeared between 1980 and 1993 and contained data on the performance of visual inspection, radiographic examination and/or FOTI in approximal caries diagnosis. Study reports which were published prior to 1980 contain data on a caries process that was markedly different from that in later years regarding appearance and progression [Wenzel et al., 1993]. The key words 'dental caries', 'approximal caries' and 'diagnosis' were entered into the literature database Medline. Additional publications were obtained from the reference sections of the publications selected by Medline. Furthermore, to survey the most recent publications, all volumes from international journals which were known to publish on the subject of caries diagnosis and which appeared during 1992 and 1993 were screened for eligible publications. The criterion for inclusion in the meta-analysis was the availability of sensitivities and specificities calculated at a cut-off for caries depth between 'caries restricted to enamel' and 'dentinal caries' in the permanent dentition in case of radiographic examination and FOTI, and between 'white/brown discoloured enamel' and 'enamel cavity' in case of visual inspection. Publications that contained data from which sensitivity and specificity values could be calculated at the previously defined cut-off were also included. Some studies compared the validity of a diagnostic test using a second diagnostic test for validation. In those cases, the validity parameters of the second diagnostic test given the performance of the first were also included. The entire procedure was carried out independently by two observers to reduce selection bias. Because the presence or absence of contact between approximal surfaces may influence the assessment of the state of disease in visual inspection, a distinction was made between visual inspection with and without tooth separation.

From each selected publication the sensitivity and specificity parameters, the study design (in vitro or in vivo experimental model) and the applied validation method(s) were recorded. Validation methods were classified into the categories 'strong' and 'weak' according to Wenzel et al. [1994]. Hence, tooth sectioning and subsequent grading of caries progression from the sections denoted 'histological validation', observation after careful cavity preparation denoted 'cavity preparation' and microradiography of tooth sections denoted 'microradiography' were considered strong validation methods. When sensitivity and specificity parameters were calculated using either visual inspection, FOTI or radiographic examination as a norm, these were considered weak validation methods.

The values of sensitivity and 1-specificity of each diagnostic test were converted into their normal deviate values, denoted Z_{caries} and Z_{sound}, respectively. Z_{caries} was subsequently plotted against Z_{sound}. In this type of ROC space, the lower-left to upper-right diagonal (slope = 1.0; see e.g. fig. 1) represents observer performance by blind chance. The distance D_z from a plotted point to this diagonal (see fig. 1) reflects the performance above chance of the diagnostic system involved or of the observer(s) using it in a single parameter [Ie and Verdonschot, 1994]. A multivariate analysis of variance with D_z as dependent variable and 'diagnostic tests', 'validation methods' and 'study design' as independent variables was subsequently conducted.

Table 1. Sensitivities and specificities of visual inspection (visual), radiographic examination (radiography) and examination upon FOTI from 14 publications, and computed D_z values quantifying the performance of the diagnostic tests above chance.

References	Diagnostic test	Study design	Validation method	Age group	Sensitivity	Specificity	Z_{caries}	Z_{sound}	D_z
Pitts and Rimmer, 1992	visual (tooth separation)	in vivo	radiography	5–15 years	0.50	1.00	0.00	–3.90	2.76
Araujo et al., 1992	visual (tooth separation)	in vivo	radiography	high-school children	0.89	0.81	1.23	–0.88	1.49
Verdonschot et al., 1991b	visual	in vitro	radiography	–	0.44	0.70	–0.15	–0.52	0.26
Sidi and Naylor, 1988	visual	in vivo	radiography	12–13 years	0.29	1.00	–0.55	–3.90	2.37
De Vries et al., 1990	visual	in vivo	radiography	14 years	0.14	1.00	–1.08	–3.90	1.99
Espelid and Tveit, 1986	visual	in vitro	radiography	–	0.94	0.46	1.55	0.10	1.03
Pieper and Schurade, 1987	visual	in vivo	FOTI	13–38 years	0.28	1.00	–0.58	–3.90	2.35
Sidi and Naylor, 1988	visual	in vivo	FOTI	12–13 years	0.42	1.00	–0.20	–3.90	2.62
Verdonschot et al., 1991b	visual	in vitro	microradiography	–	0.50	0.71	0.00	–0.55	0.39
Peers et al., 1993	visual	in vitro	histology	–	0.38	0.99	–0.31	–2.33	1.43
Bille and Thylstrup, 1982	radiography	in vivo	cavity preparation	8–15 years	0.57	0.88	0.18	–1.17	0.95
Espelid and Tveit, 1986	radiography	in vitro	cavity preparation	–	0.59	0.93	0.23	–1.48	1.21
Thylstrup et al., 1986	radiography	in vivo	cavity preparation	all ages	0.74	0.85	0.64	–1.04	1.19
Sidi and Naylor, 1988	radiography	in vivo	visual	12–13 years	0.36	0.99	–0.36	–2.33	1.39
De Vries et al., 1990	radiography	in vivo	visual	14 years	0.90	0.98	1.28	–2.05	2.35
Verdonschot et al., 1991b	radiography	in vitro	visual	–	0.20	0.90	–0.84	–1.28	0.31
Espelid and Tveit, 1986	radiography	in vitro	visual	–	0.43	0.95	–0.18	–1.64	1.03
Sidi and Naylor, 1988	radiography	in vivo	FOTI (bucc.)	12–13 years	0.28	1.00	–0.58	–3.90	2.35
Mitropoulos, 1985a	radiography	in vivo	FOTI	5–43 years	0.91	0.99	1.34	–2.33	2.60
Sidi and Naylor, 1988	radiography	in vivo	FOTI (ling.)	12–13 years	0.29	0.99	–0.55	–2.33	1.26
Pieper and Schurade, 1987	radiography	in vivo	FOTI	13–38 years	0.35	0.98	–0.39	–2.05	1.17
Stephen et al., 1987	radiography	in vivo	FOTI	13–14 years	0.52	0.98	0.05	–2.05	1.48
Stephen et al., 1987	radiography	in vivo	FOTI	13–14 years	0.67	0.97	0.44	–1.88	1.64
Mitropoulos, 1985b	radiography	in vivo	FOTI	12–13 years	0.83	0.98	0.95	–2.05	2.12
Russel and Pitts, 1993	radiogr. digital	in vitro	histology	–	0.16	0.96	–0.99	–1.75	0.54
Russel and Pitts, 1993	radiogr. D-speed	in vitro	histology	–	0.29	0.92	–0.55	–1.41	0.61
Russel and Pitts, 1993	radiogr. E-speed	in vitro	histology	–	0.30	0.96	–0.52	–1.75	0.87
Peers et al., 1993	radiography	in vitro	histology	–	0.59	0.96	0.23	–1.75	1.40
Verdonschot et al., 1991b	radiography	in vitro	microradiography	–	0.50	0.94	0.00	–1.55	1.10
Mitropoulos, 1985a	FOTI	in vivo	radiography	5–43 years	0.85	1.00	1.04	–3.90	3.49
Mitropoulos, 1985b	FOTI	in vivo	radiography	12–13 years	0.73	0.99	0.61	–2.33	2.08
Pieper and Schurade, 1987	FOTI	in vivo	radiography	13–38 years	0.71	0.92	0.55	–1.41	1.39
Stephen et al., 1987	FOTI	in vivo	radiography	13–14 years	0.44	0.99	–0.15	–2.33	1.54
Stephen et al., 1987	FOTI	in vivo	radiography	13–14 years	0.38	0.99	–0.31	–2.33	1.43
Sidi and Naylor, 1988	FOTI (bucc.)	in vivo	radiography	12–13 years	0.74	0.99	0.64	–2.33	2.10
Sidi and Naylor, 1988	FOTI (ling.)	in vivo	radiography	12–13 years	0.30	0.99	–0.52	–2.33	1.28
Sidi and Naylor, 1988	FOTI	in vivo	visual	12–13 years	1.00	0.99	3.90	–2.33	4.41
Pieper and Schurade, 1987	FOTI	in vivo	visual	13–38 years	0.96	0.92	1.75	–1.41	2.23
Peers et al., 1993	FOTI	in vitro	histology	–	0.67	0.97	0.44	–1.88	1.64

Results

The literature search and selection procedure resulted in 14 publications containing data which complied with all criteria. From these publications, 39 sets of sensitivity and specificity values were obtained or calculated. The selected publications are listed in table 1, together with the reported or calculated sensitivities, specificities and corresponding D_z values. Values of Z_{caries} plotted against Z_{sound} are depicted in figure 1. The mean sample size of studies with a weak validation method was 7,471 and 222 for those using a strong validation method. Mean sample size in vitro studies was 155 and 8,061 for in vivo studies. Table 2 contains the mean D_z values for the diagnostic systems un-

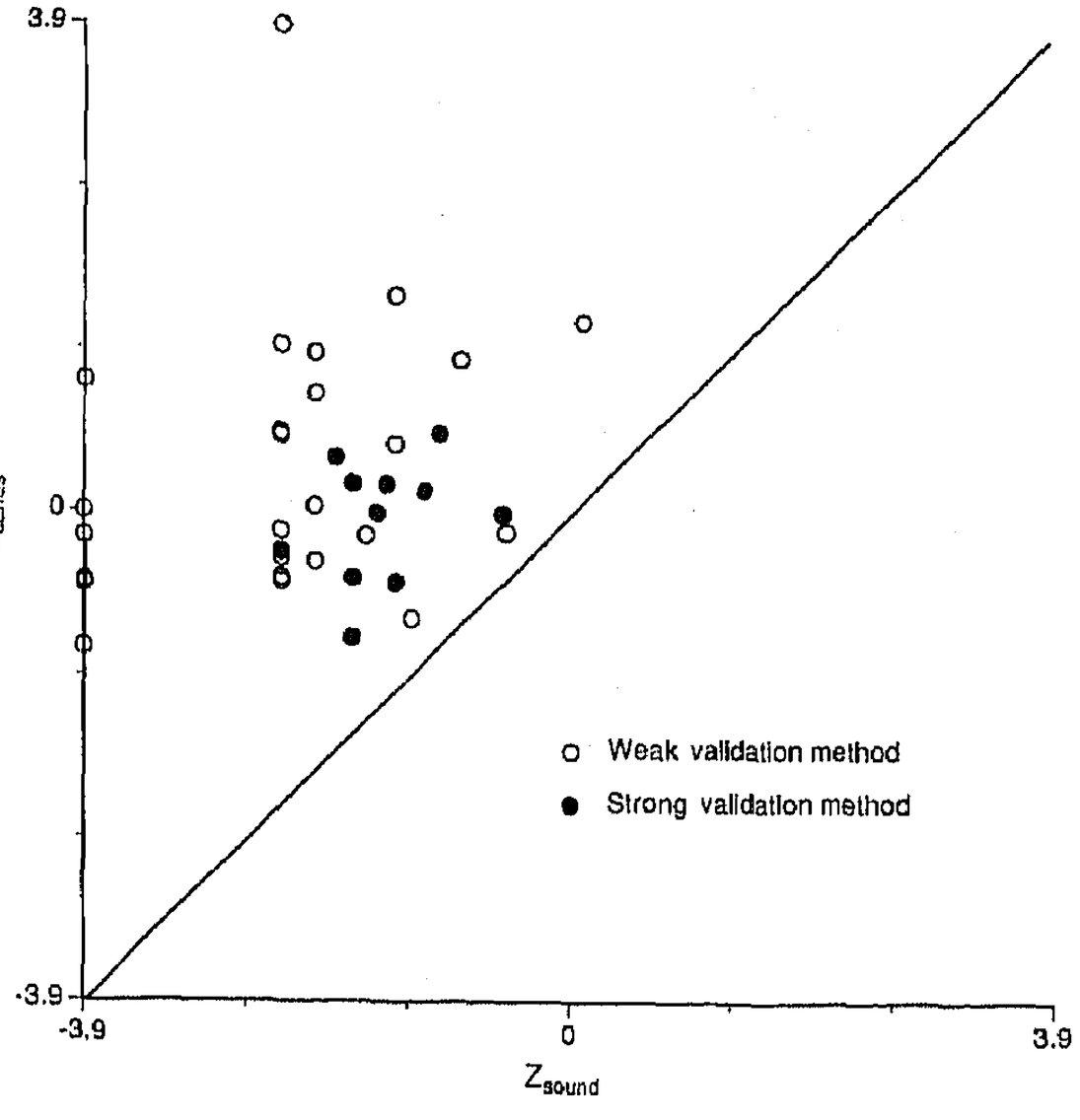

Fig. 2. D_z values of three diagnostic tests in approximal caries diagnosis, with a distinction between weak and strong validation methods.

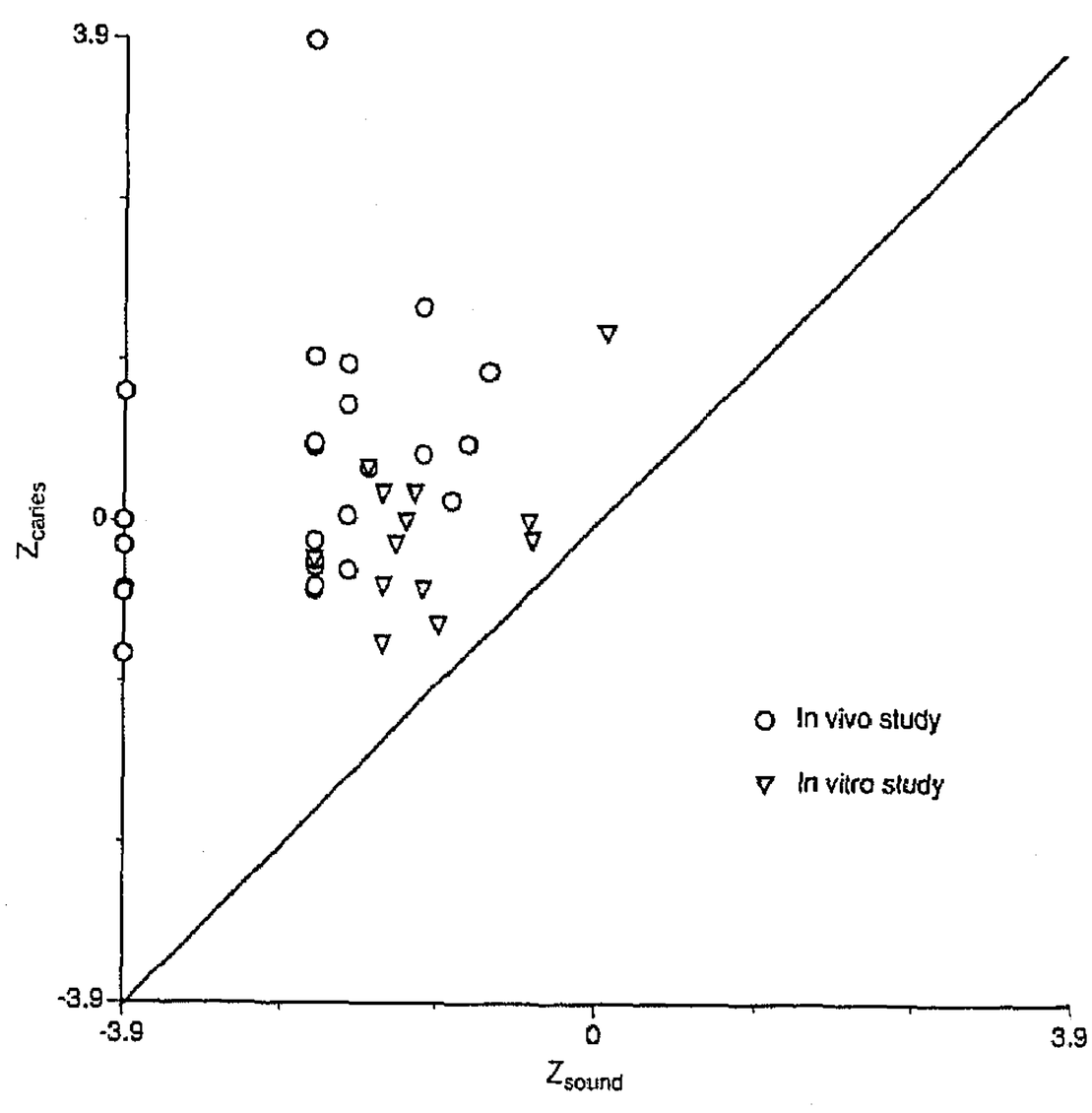

Fig. 3. D_z values of three diagnostic tests in approximal caries diagnosis, with a distinction between the in vivo and the in vitro study model.

der study. The mean D_z values suggest that the validity of FOTI diagnosis and visual inspection after tooth separation are superior to those of visual inspection and radiographic diagnosis. The range of D_z values indicates the diversity in study results.

The mean D_z values and corresponding standard deviation of the diagnostic systems are cross-tabulated against study design (in vitro and in vivo) and the validation method (strong and weak) in table 3. On average, weak validation methods yield higher values of D_z than strong validation methods (fig. 2), and D_z values which originate from in vivo studies are higher than those from in vitro studies (fig. 3).

The results of a multivariate analysis of variance with D_z as dependent, normally distributed variable are presented in table 4. D_z values were neither statistically significantly different between 'diagnostic tests' nor between 'validation methods' ($p>0.05$), indicating that D_z was neither significantly affected by the type of diagnostic system nor by the validation method. D_z values obtained from in vivo studies were significantly different from those obtained from in vitro studies ($p<0.05$), indicating that study design had a significant impact on the measurement of the validity of the diagnostic tests.

Table 2. Mean D_z values, standard deviations and ranges indicating the average performance above chance from various diagnostic tests in approximal caries diagnosis

Diagnostic test	Mean D_z	SD	Range	
			low	high
Visual inspection (tooth separation)	2.12	0.89	1.49	2.76
Visual inspection	1.55	0.92	0.26	2.61
Radiographic examination	1.35	0.63	0.31	2.60
FOTI examination	2.16	1.02	1.28	4.41

Discussion

The problems of the interpretation of the sensitivity and specificity of a diagnostic test have been addressed by many investigators. Two methods currently exist to evaluate sensitivity and specificity simultaneously, i.e. logistic regression and ROC analysis [Berkey et al., 1990]. Logistic regression analysis, however, is only suitable when large data bases are available. ROC analysis is a very appropriate method when less extensive data bases are present [Verdon-

Table 3. Mean D_z values and standard deviations indicating the average performance above chance of various diagnostic tests in approximal caries diagnosis cross-tabulated against an in vivo or in vitro study model and the use of weak or strong validation methods

Diagnostic test	In vivo		In vitro		Weak validation		Strong validation	
	mean D_z	SD	mean D_z	SD	mean D_z	SD	mean D_z	SD
Visual inspection (tooth separation)	2.13	0.90	–	–	2.13	0.90	–	–
Visual inspection	2.33	0.26	0.78	0.55	1.77	0.93	0.91	0.74
Radiographic examination	1.68	0.57	0.88	0.37	1.48	0.69	0.98	0.30
FOTI examination	2.22	1.07	1.64	–	2.22	1.07	1.64	–

schot et al., 1993b]. D_z values used in this meta-analysis were derived from combinations of sensitivity and specificity projected in ROC space and therefore evaluated sensitivity and specificity simultaneously. By measuring the distance from these projections to the diagonal which respresents the set of points with indifferent distinction between true and false diagnostic test results, sensitivity and specificity are weighed equally important. When applying a diagnostic test to a specific task, e.g. the diagnosis of approximal caries reaching the dentine in low caries prevalence individuals, it may be considered more important to avoid false-positive test results, hence to use a diagnostic test with a high specificity. Since a high value of specificity is usually obtained at the expense of a low sensitivity, the increased number of false-negative results should thus be accepted. Diagnostic strategies that emphasize high sensitivity or high specificity, which were present in some of the studies included in the meta-analysis, were ignored in using D_z in this meta-analysis.

More generally, if the true-positive and false-positive diagnostic test outcomes were both normally distributed with equal variances, the ROC graph plotted on normal deviate axes would be a straight line with slope = 1, i.e. parallel to the diagonal in figure 1. In this particular case, all D_z values would be equal, irrespective of disease cut-off. Because the true-positive and false-positive distributions could not be obtained from most publications, it was assumed that D_z was dependent on the disease cut-off, and, therefore, sensitivities and specificities calculated from only one disease cut-off were used in this meta-analysis.

Most clinicians use bite-wing radiography additional to visual inspection. It is evident that this strategy will emphasize the detection of carious lesions in addition to those found by visual inspection, thus improving the sensitivity of the combined tests. Caries lesions which do not appear as radiolucencies on radiographs (false-negative) but were found upon visual inspection, will very likely be ignored

Table 4. Analysis of variance for D_z with diagnostic test, study design and validation method as independent variables

	d.f.	Sum of squares	Mean square	F ratio	Probability
Diagnostic test	3	2.92	0.97	2.15	0.12
Study design	1	2.89	2.89	6.39	0.02
Validation method	5	3.10	0.62	1.37	0.26
Error	29	13.11	0.45		
Total	38	28.21			

and therefore do not decrease the specificity of the combined tests. In general, the use of one test additional to another will improve the accuracy. However, in the studies selected for the present meta-analysis, the validity of radiographic caries diagnosis was measured independently of any other test. Therefore, false-positive results due to irregularities in projective geometry and false-negative ones due to approximal overlap and lack of radiation contrast will result in a relatively low validity of radiographic diagnosis compared to the use of radiography in addition to visual inspection. This could explain the fairly low performance of radiographic examination found in this study.

The finding that, on average, FOTI diagnosis had superior D_z values is partly caused by the fact that all but one of the included studies on FOTI applied both an in vivo study design and a weak validation method. The applied study design and validation method might have overestimated the performance of FOTI. This assumption was supported by the results of the analysis of variance which indicates that the variance in D_z could not be explained by the type of diagnostic test employed. It is also important to note that no statistically significant differences were found between the reported accuracies of the diagnostic methods under investigation. In some of the included studies in which three

or more of the diagnostic tests were evaluated, significant differences between various methods were indeed demonstrated. It should be kept in mind that in those investigations study design as well as validation method were fixed, i.e. did not introduce variance to the diagnostic measurements.

The method for obtaining a 'gold standard' diagnosis, which was found to have a significant impact on the results of diagnostic tests in occlusal caries diagnosis [Wenzel et al., 1994], did not significantly influence diagnostic performance represented by D_z in this study. In their study, Wenzel et al. [1994] only investigated the influence of microscopic, histological and microradiographic observations from tooth sections as validation methods, which were all considered strong validation methods in the present study. In addition, only material from in vitro studies was used by Wenzel et al., thus eliminating a major source of variance because, according to the results of this meta-analysis, study design significantly affects the validity measurement of the diagnostic test. 'Study design' was the only variable that could significantly explain the variance in the distribution of D_z. Table 3 shows that the average D_z of visual inspection from in vivo studies was three times higher than that from in vitro studies, whereas the D_z of radiographic examination from in vivo studies was, on average, twice that of in vitro studies. These differences were magnified by the almost exclusive use of weak validation methods in in vivo studies and of strong validation methods in in vitro studies. It is understandable from an ethical point of view that predominantly weak validation methods like radiography and visual inspection are used in in vivo studies. Yet, mathematical models exist to relate the radiographic diagnoses obtained from children to the true 'state of decay' [Verdonschot et al., 1991a]. The observers who diagnosed caries from bite-wing radiographs in in vivo studies are asked to diagnose caries from radiographs taken from a set of teeth under well-simulated in vitro conditions. These obtained diagnoses are subsequently validated by a strong validation method. Based on the misclassification of radiographic diagnosis given a strong validation method, the validity of the diagnostic system as measured in the in vivo study conducted can then be adjusted.

Differences between D_z values from in vivo and in vitro studies could furthermore be related to the origin of the teeth used, to differences in the prevalence of caries in the samples and to the simulation techniques applied in in vitro studies. Most in vivo studies were carried out in 5- to 15-year-old children (table 1) with a low caries prevalence and only few obvious, 'easy-to-find' caries lesions, which probably caused an overestimation of the specificity of the diagnostic tests in in vivo studies. It is suggested from this meta-analysis that the conditions under which future diagnostic in vitro studies are conducted be natural simulations of those under which the tests will be applied in patients. To enable researches to 'standardize' the outcomes of their diagnostic studies, it is further advocated that the relationship between diagnostic test, study design, validation method and disease cut-off be contained in a mathematical model.

It is concluded from this meta-analysis that the influence of the in vivo or in vitro study design outweighs the measurement of the validity of the diagnostic method in approximal caries detection.

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