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Detection and Activity Assessment of Primary Coronal Caries Lesions: A Methodologic Study

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Clinical Relevance

The results from this study indicate that it is possible to predict lesion depth and assess the activity of primary coronal caries lesions accurately by using the combined knowledge obtained from the visual appearance, location of the lesion and tactile sensation during probing.

SUMMARY

This study has three main objectives: Study 1) test the reproducibility and accuracy of the ICDAS I and ICDAS II caries detection systems; Study 2) validate a new impression material (Clinpro, 3M ESPE), which is said to detect lactic acid in plaque fermenting sucrose; Study 3) devise and test a scoring system for the assessment of caries activity of coronal lesions.

Study 1): 141 extracted teeth were examined by two examiners using the ICDAS I and ICDAS II caries detection systems and validated against a histological classification system. Study 2): The accuracy of the impression material in predicting plaque with pH lower/higher than 5.5 was determined in an *in situ* study of 45 root dentin specimens by comparing the color change in the impression with the actual pH of the plaque, determined with a pH meter. Study 3): A scoring system to assess lesion activity was devised based on the predictive power of the visual appearance of the lesion (ICDAS II system), location of the lesion in a plaque stagnation area and, finally, the tactile feeling, rough/soft or smooth/hard, when running a perio-probe over the lesion. The accuracy was tested in a clinical

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study of 35 children with 225 lesions/sound surfaces and was validated using the Clinpro impression material for construct validity.

Study 1): Intra- and inter-examiner reproducibility was found to be excellent (Kappa-values >0.82) and the associations strong (Spearmans correlation coefficients >0.90). Study 2): The Clinpro impression material was found to be acceptable as compared to the results of a pH meter, the combined sensitivity and specificity was 1.63. Study 3): ROC analysis showed that the devised classification system for determining lesion activity had acceptable accuracy (area under curve = 0.84 and the highest combined sum of specificity and sensitivity was 1.67).

Thus, it is possible to predict lesion depth and assess the activity of primary coronal caries lesions accurately by using the combined knowledge obtained from visual appearance, location of the lesion and tactile sensation during probing.

INTRODUCTION

A systematic review of the literature presented at the National Institutes of Health (NIH) consensus development conference on "diagnosis and management of dental caries throughout life," held in Bethesda, MD, USA, in 2001, came to the conclusion that reliability and reproducibility of currently available caries detection/diagnostic systems, including visual and visual-tactile criterion, were not strong.[1] In addition, the final document from the International Consensus Workshop on Caries Clinical Trials, held in Glasgow, Scotland in 2002, agreed in principle with this statement.[2] Based on this, an international group of researchers founded the International Caries Detection and Assessment System (ICDAS) later in the same year, with the mission to devise an internationally accepted caries detection system that would also allow assessment of caries activity. As a result of discussions within the founding committee and pilot studies, the ICDAS I caries detection system was devised in 2003. Based on feedback from approximately 70 participants from around the world who met at the ICDAS workshop in Baltimore in 2005, this was modified to form what is now known as the ICDAS II system.[3]

The fundamental principle underpinning the system is that the examination should be carried out on clean, plaque-free teeth, as recommended by a number of authors.[4-5] Furthermore, careful drying of the surface/lesion in question is considered important in identifying very early lesions.[3-5] Finally, a ball-ended periodontal probe should replace traditionally used explorers and sharp probes, because the latter can produce traumatic defects when used on incipient lesions,[6] and explorers and sharp probes have been shown to add little information to a visual examination alone.[7] A number of large scale studies are currently being carried out to confirm the reproducibility and accuracy of the ICDAS detection systems, with a final score system for activity assessment under development.

To date, little attention has been devoted to the validity of visual/tactile systems in the assessment of caries activity.[8-9] The first study was a small scale study performed on Danish adults that focused only on occlusal lesions.[8] The second, larger scale study, was performed on children in Lithuania, taking all tooth surfaces into consideration.[9] The system developed by Nyvad and others[9] used a visual-tactile concept and examined unclean plaque-covered teeth, which might lead to a number of lesions being missed.[4-5] The activity status of a lesion was judged based on plaque accumulation, visual appearance and tactile feeling when the lesion was probed. All three criteria should point in the same direction. For example, a white spot lesion, rough to probing and plaque covered, is judged as an active lesion, while a brown spot lesion, smooth to probing and without plaque, is judged as an arrested lesion. The reproducibility and predictive validity of the system are both reported as high, but the authors state that it is hard to judge between sound and incipient lesions. Furthermore, the study does not discuss how decisions were recorded in cases where all the criteria do not point in the same direction, for example, a white spot lesion covered by plaque but smooth to probing. This is a potential problem, as white spot lesions smooth to probing or brown spot lesions rough to probing, were often recorded by three different clinicians in a study performed by Ekstrand and others.[10]

In contrast to lesion severity, which can be validated histologically or operatively, presently, there is no accepted gold standard that can be used to differentiate between an active or an arrested lesion upon single examination. To overcome this lack of an accepted gold standard, "construct validity" can be used.[11] This is where a known theoretical condition or situation, which is associated with caries activity, is used as the gold standard. For example, it is widely accepted that fluoride promotes remineralization and a reduction in the caries progression rate.[12] The known remineralizing effect of fluoride can therefore act as "construct validity" according to Nyvad and others.[13] Similarly, it is known that the critical pH at which enamel dissolves is 5.5 or below and that methyl red, a pH-indicator, changes color around this pH.[14] Thus, clinical assessment of the activity of a lesion on a tooth deemed for extraction can be validated by histological examination with methyl red dye.[8,15]

Recently, a new impression material has been introduced, which can detect lactic acid produced in metabolically active plaque by a color change within the material (Clinpro Cario Diagnosis, Full Arch Lactic Acid Locator, 3M ESPE).[16] Lactic acid formation is fundamentally associated with demineralization of hard dental tissue.[17] As such, this impression technique has the potential to be used as construct validity for lesion activity and may be useful in further research on lesion activity.

In three separate studies, this paper aims to:

1) Determine the accuracy and reproducibility of the ICDAS I and ICDAS II caries detection systems for coronal primary caries *in vitro*.
2) Determine the accuracy of the potential construct validity technique, namely the Clinpro impression material, *in situ*.
3) Devise a system for determining lesion activity based on: 1) the ICDAS detection criteria, 2) using a surrogate for the presence of plaque and 3) the tactile feeling when probing the lesion and test this in an *in vivo* study using Clinpro impression material as construct validity.

METHODS AND MATERIALS

Study 1. Histologic Validation of ICDAS II Criteria

One hundred and forty-one extracted teeth were collected from clinics in Dundee, Scotland and Copenhagen, Denmark at the end of 2003. The teeth were cleaned, stored in thymol and lesions were selected on smooth, proximal and occlusal surfaces. A total of 141 lesions were classified independently by two of the authors, initially according to the ICDAS I detection system but they were later re-arranged to the ICDAS II detection system (Table 1, left section). The only differences between the two systems were that shadowed lesions (score 3) and the micro-cavitated lesions (score 4) in ICDAS I were switched in ICDAS II; thus, micro-cavitated lesions became score 3 and shadowed lesions became score 4 in the ICDAS II detection system (Table 1). All the teeth were re-examined to determine intra-examiner reproducibility.

The teeth were then sectioned through the investigation site to produce three sections of each lesion, and the section with the deepest aspect of the lesion was chosen for histological examination.[5] The selected sections were examined under stereomicroscope at 5x magnification individually by both investigators. Caries on the sections was classified according to the histological classification system presented in Table 1 (right section).

Study 2: Validation of the Impression Material

Nine people, ranging in age between 49 and 66 years, each with a partial denture in the lower jaw, participated in a pilot study to examine the clinical effect of Ozone treatment. Ethical approval was obtained from The Frederiksbergs Ethical Board and written consent was obtained from the participants. Each of the participants had three (n=8) or two (n=1) dentin specimens inserted into their partial denture for a period of six weeks. To encourage plaque growth on the dentin sample surface, the participants placed the denture in a 10% sucrose solution for 10 minutes three times a day.[19]

For purposes of this study, the pH at the surface of each tooth specimen was measured after three weeks using a pH-meter (MI-406 flat membrane pH electrode, Radiometer, Denmark). Prior to pH measurement, the denture was placed in a 10% sucrose solution for 30 seconds. The pH measurement was made after an additional three minutes,[17] and each reading was recorded to one decimal place. Finally, impressions were taken with the Clinpro material, taking care that the material was pressed in firm contact to each tooth specimen. Once set and the denture removed, the color of the impression material was noted in relation to the dentin sample. If the material changed to a deep blue color, indicating lactic acid production, a positive signal was recorded; if the material maintained its original color, no signal was recorded (no lactic acid). This was repeated after an additional three weeks, thus, a total of 52 tests were made.

Table 1: *ICDAS II Caries Detection System and Histologic Caries Classification System*

Code	ICDAS II (3)	Histological Classification System (18)
0	Sound tooth surface	No demineralization
1	First visual change in enamel: 1w (white) or 1b (brown)	Demineralization limited to the outer 1/2 of the enamel thickness
2	Distinct visual change in enamel: 2w (white) or 2b (brown)	Demineralization between inner 1/2 of the enamel and outer 1/3 of the dentin
3	Localized enamel breakdown due to caries with no visible dentin or underlying shadow	Demineralization in the middle third of the dentin
4	Underlying dark shadow from dentin with or without localized enamel breakdown	As above
5	Distinct cavity with visible dentin	Demineralization in the inner third of the dentin
6	Extensive distinct cavity with visible dentin	As above

Table 2: *Activity Predictor Based on Lesion Location*

Lesion located in a natural cariogenic plaque stagnation area: (PSA)	**Lesion located in a not related natural plaque stagnation area: (non-PSA)**
Occlusal surfaces: Erupting posterior teeth: The entire occlusal surface Erupted posterior teeth in occlusion: Fossae or fissures where a ball ended probe can enter	Occlusal surfaces: Erupted posterior teeth in occlusion: Narrow fossae and fissures where a ball ended probe cannot enter either because they are too narrow or too wide (no depth)
Buccal and linqual surfaces: 0- 400 µm from gingival margin measured by the ball ended probe	Buccal and linqual surfaces: > 400 µm from gingival margin measured by the ball ended probe
Proximal surfaces: Between contact area and gingiva	Proximal surface No adjacent tooth
In addition: Frank cavities with irregular borders	In addition: Open frank cavities with regular borders located away from a natural plaque stagnation area

Table 3: *Activity Predictor Based on Tactile Feeling (ball-ended probe)*

	Rough/Soft	**Smooth/Hard**
Enamel	The enamel is obviously rough due to caries and this roughness is not due to staining/partly mineralized debris/calculus/anatomy.	The enamel is smooth to probing. Superficial defects are accepted if they are open and the borders are smooth to probing. Roughness is accepted if it is due to staining partly mineralized debris/calculus.
Dentin	The exposed dentin is rough/soft to probing and/or an irregular breakdown/ defect is detected with the ball-ended probe.	The dentin is hard to probing.

Study 3. Clinical Study Using a Newly Devised Activity Assessment System

In order to devise a system to assess the caries activity of primary coronal caries *in vivo*, three clinical parameters were suggested: the visual appearance of the lesion (the ICDAS II scores, Table 1): the location of the lesion as seen from the viewpoint of a potential plaque stagnation area (Table 2) and the tactile sensation of the lesion when a periodontal probe is gently run over the lesion (Table 3).

The population targeted in this study was children between the ages of 5 and 11 years (median age 8) attending schools in Bogotá, Colombia. Ethical approval for the study was gained from the ethical board at the U El Bosque in Bogotá. One investigator explained the purpose and logistics of the study to the head teachers of two primary schools in Bogotá. A total of 36 children/parents (19 boys and 17 girls) gave written consent to take part in this study.

After brushing their teeth, the children were examined by one of the authors. The examination took place in the playroom of each school using a portable light, compressed air and a 3-in-1 syringe, a dental mirror and a ball-ended probe. The inclusion criteria were that each child had one or more carious lesion in either primary or permanent teeth and that the study group, overall, had lesions representing a range of appearances from initial brown and white spot lesions to extensive cavitation. A number of clinical sound surfaces were also included. A total of 35 participants met the inclusion criteria, providing 225 lesions/sound surfaces suitable for the study.

Assessment of Caries Activity

At another appointment, the lesions were classified according to the ICDAS II scoring system (Table 1). Next, they were classified according to their location as either being in a plaque stagnation area (PSA) or not in a plaque stagnation area (non PSA) as described in Table 2. Finally, the tactile sensation of the lesions was determined by gently drawing a probe across the lesion and assessing it as either rough/soft or smooth/hard, as described in Table 3.

Reproducibility

Three days after the initial examination, five children with 36 lesions/sound surfaces (16%) were randomly selected for re-examination in order to determine intra-examiner reproducibility.

Impression

After approximately one week, impressions were taken of all tooth surfaces under investigation, using the impression-based diagnostic material described by Schmid and others[16] (Clinpro Cario Diagnosis, Full Arch Lactic Acid Locator, 3M ESPE). This required the participant or his or her parent/guardian to brush the teeth as per their normal routine prior to taking the

Table 4: *Relationship between ICDAS II scores and histological changes for examiner 1. Study 1.*

		Histological Classification					
		Code 0	Code 1	Code 2	Code 3	Code 4	Total
ICDAS-II Codes	Code 0	35	2				37
	Code 1	3	16	1			20
	Code 2		3	21	5		29
	Code 3			4	7	2	13
	Code 4			1	7	1	9
	Code 5				5	13	18
	Code 6					13	13
	Total	38	21	27	24	29	139

impression. Once set, the impression material was pale blue; however, those areas corresponding to a lactic acid producing plaque changed to a dark blue color. Photographs were taken of the impressions in the areas corresponding to the selected surfaces where the lesions were located. The impressions were then inspected. A lesion which corresponded to a blue color change in the impression material (signal), due to lactic acid producing plaque, was then classified as active, while a lesion corresponding to no color change in the impression material (no signal) was classified as inactive.

Distribution of the Final Sample

Three children refused to have impressions taken and, in a number of cases, the impressions had air bubbles in the investigation sites, in particular, in cases with cavitation. This left a total of 26 participants with 176 lesions/sound surfaces (range 1-13 cases; median = 8) who completed the study and had perfect impressions taken. Of these 176 cases, 127 (72%) were on primary teeth and 49 (28%) were on permanent teeth. Sixty-seven investigation sites (38%) were on occlusal surfaces, 99 (56%) were on smooth surfaces (62 gingival, 23 in pits and 14 on approximal surfaces) and 10 lesions (6%) extended over more than one surface.

STATISTICS

Study 1. Detection

Intra- and inter-examiner reproducibility was assessed using Kappa statistics. The relationship between the ICDAS detection systems and histological classification (Table 4) were determined using the Spearman correlation coefficient.

Study 2. Validation of the Impression Material

The pH-threshold 5.5 was used to differentiate active plaque/lesions (pH≤5.5) from inactive plaque/lesions (pH>5.5) (Table 5). The accuracy of the material was expressed by means of specificity and sensitivity.

Study 3. Clinical Study

The lesions were scored according to the ICDAS II scoring system and the prevalence of each score was determined.

Devising the Activity Scoring Systems

In this part of the study, the sound surfaces were excluded (n=34), giving a total of 142 lesions. The lesions scored by the ICDAS II detection system were rearranged into three categories: A) any brown spot lesion, B) any white spot lesion and C) any shadowed/cavitated lesion. To reduce the risk of a large number of lesions in one particular category, possibly skewing the results, it was decided to have even numbers in each group. The smallest category was for white spot lesions (n=41); therefore, 41 lesions were randomly chosen from each of the remaining categories, giving a subsample of 123 lesions. For each of the three clinical parameters investigated, namely, visual appearance in terms of A, B or C lesions, location of the lesion and tactile sensation, the predictive power of each sub-classification in determining whether a lesion was active was calculated. This was done by expressing the number of lesions in each sub-classification that corresponded to a color change in the impression material as a percentage of the total number within the sub-classification (Table 6). In order to establish the final scoring system to determine lesion activity, the predictive power percentage scale was divided into a four-point scoring system (1 point if the predictive power was within the range of 0-25%; and 2-, 3- and 4-points if the predictive power was within the range of 26-50%; 51-75% or 76-100%, respectively. For example, the predic-

Table 5: *Data dichotomized into no signal or signal and pH≤5.5 and pH>5.5. Study 2.*

	pH≤5.5	pH>5.5	Total
No signal	1	12	13
Signal	26	6	32
Total	27	18	45
	Sensitivity 26/27=0.96	Specificity 12/18=0.67	

tive power of a brown spot lesion in determining lesion activity is 15% (6/41) and therefore receives 1 point (Table 6).

Diagnostic Accuracy of the New Scoring System

For each lesion under investigation in this study, the visual appearance, location and tactile sensation were recorded as described, together with the corresponding score and, finally, a cumulative score was calculated. Using the blue signal from the impression material as construct validity, the sensitivity and specificity was determined using different threshold or cumulative score cut-off points. There were six theoretically diagnostic thresholds or cut-off points possible upon which to determine the sensitivity and specificity: cases with four points versus cases > four points, cases with four or five points versus cases > five points, etc. Using these thresholds, a ROC curve was constructed and the area beneath the curve, the standard error and the optimum cut-off were determined.

Intra Examiner Reproducibility

Intra-examiner reproducibility was expressed by Kappa values and percent agreement. The latter statistic is the level of exact agreement between the first and second recordings expressed as a percentage.

The Influence of the Individual

In this study, more than one lesion from each participant was used, and it may be argued that this does not represent independent data. To address this, the validity of using only one randomly selected lesion from each of the 26 participants was assessed. The corresponding response from the impression material and the cumulative score for each lesion was used to prepare a ROC-curve. The areas below the ROC-curves were compared statistically using the 95% confidence intervals to see if they differed significantly from each other.

RESULTS

Study 1. Detection Study

A total of 141 teeth were included in this study. However, two teeth were finally excluded, as sections broke during the sectioning technique. From the 139 remaining teeth, the association between ICDAS I scores for all surfaces and histological depth of the lesion (rs) for both examiners was found to be strong (rs=0.94 and 0.89). Corresponding figures were obtained when the ICDAS II scoring system was used (rs= 0.96 and 0.91). Whether the ICDAS I or ICDAS II system was used made little difference to these results. As the ICDAS II system is the most recently accepted version, it alone will be used in the rest of this study and, because the there is little difference between examiners, the results for Examiner 1 only are presented in Table 4 for illustrative purposes.

When the sample was split into proximal surfaces (n=57), the correlation coefficients for both examiners were rs=0.93 and 0.92, for occlusal surfaces (n=42) rs=0.94 and 0.90 and for smooth surfaces (n=40) rs=0.94 and 0.91. Intra-examiner reproducibility was found to be substantial (Kappa = 0.82 and 0.87), as was inter-examiner reproducibility (Kappa = 0.82).

Study 2. The Validation of the Impression Material

A total of 52 pH measures were conducted on two occasions on the nine patients. In four cases, the pH meter did not give a stable reading and, in three cases, there were bubbles in the impression material, leaving 45 pH measurements and corresponding impressions for investigation (Table 5). The pH-values varied in the 45 cases between 3.10 and 6.82. Internal analyses disclosed that the pH within the patient could vary more than 1 pH-value (5.74-4.60).

Using the selected pH-threshold of 5.5 (the critical pH) as the gold standard for the signal from the Clinpro impression material, sensitivity was found to be 0.96 and specificity 0.67.

Study 3. Clinical Study

The distribution of ICDAS II scores in the clinical study (n=176) was as follows: 19% were sound surfaces, 15% were lesions requiring air drying to become visible (code 1: 2 were code 1w and 24 code 1b, Table 1), 34% were visible without air drying (code 2: 39 were code 2w and 20 code 2b, Table 1), 15% had microcavitation (code 3), 3% had shadows (code 4), 5% had a distinct cavity (code 5) and, finally, 10% had a profound cavity (code 6). Thus, 44 lesions were brown spots (code 1b, 2b), 41 lesions were white spots (1w, 2w), 51 had different kinds of cavitation and 5 had shadows.

Table 6: *Predictive power calculations using the three clinical parameters and the related points. Study 3 clinical parameter N power scoring system*

Visual Appearance	**123**	**Impression Signal n (%)**	**0- 25%= 1 point 26-50%= 2 points 51-75%= 3 points 76-100%= 4 points**
A: Brown spot	41	6(14.6%)	1
B: White spot	41	21(51.2%)	3
C: Shadows and any cavitation	41	34(82.9%)	4
Plaque Stagnation Area	**123**		
No	52	11(21,2%)	1
Yes	71	49(69.0%)	3
Tactile Sensation	**123**		
Smooth/hard	79	26(32.9%)	2
Rough/soft	43	35(81.4%)	4

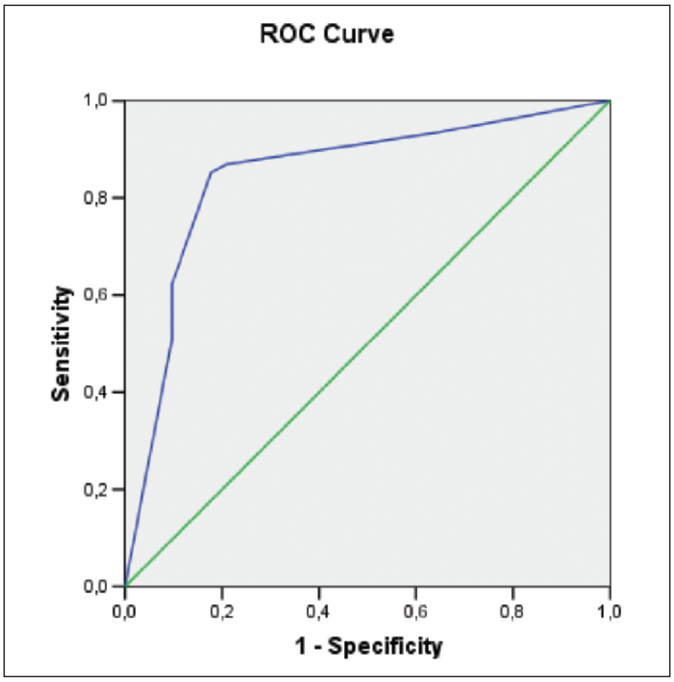

Figure 1a*: A ROC-curve of the scoring system using the 123 selected lesions.*

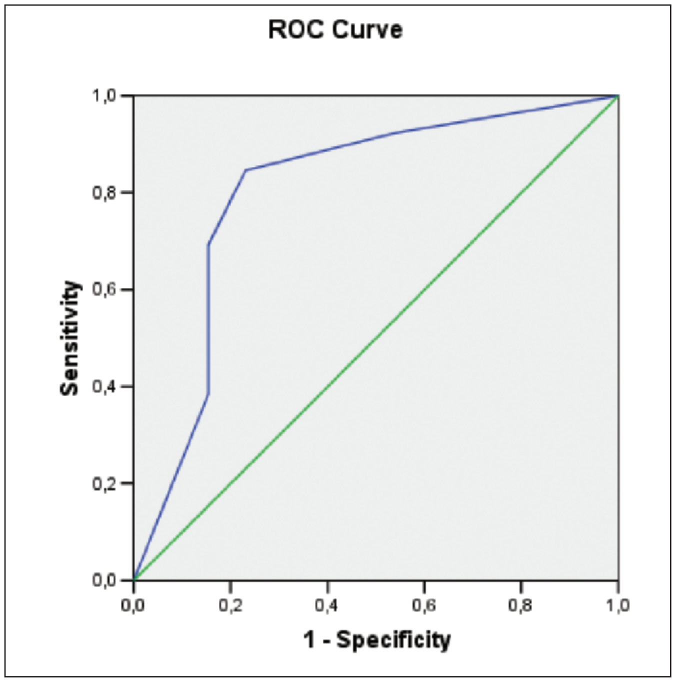

Figure 1b*: A ROC-curve when only one lesion from each participant (n=26) was used.*

Of all 176 lesions/sound surfaces, 107 (61%) were in plaque stagnation areas and 54 (31%) were rough/soft to probing.

The Intra-examiner Reproducibility

The Kappa value/percent agreement concerning the visual appearance was 0.87/0.90, for the location of the lesion 0.63/0.84 and for the tactile sensation 0.63/0.82.

Activity Assessment

Table 6 shows the relation among the individual subclasses in the three clinical parameters and the number with a signal in the impression material in the 123 selected lesions (41 brown-, 41 white- and 41 shadowed/cavitated lesions). Using these data, 6 (15%) of the brown spot lesions had a corresponding signal in the impression material. The predictive power was therefore 15%, which corresponded to 1 point on the 4-point scale. The predictive powers of white spots and shadowed/cavitated lesion were 51% (3 points) and 83% (4 points), respectively. The predictive power of plaque stagnation areas (PSA/no PSA) and tactile feeling (smooth/hard) are presented in Table 6.

Figure 1a shows the ROC curve generated for all of the included teeth. The area under the ROC curve was 0.85. The area differed significantly from that under the diagonal ($p<0.05$) and, therefore, the scoring system was significantly better at detecting lesion activity than by chance alone. The highest combined sum of specificity and sensitivity was 1.67 (threshold between 7 and 8 points) followed by 1.66, when the threshold was between 6 and 7 points.

The Influence of the Individual

The area under the curve was 0.81 (Figure 1b) (95% confidence interval 0.621-0.988) when using only one randomly selected lesion from each participant, and it did not differ from that calculated when using the total material (0.85, 95% confidence interval 0.774-0.922; $p>0.05$).

DISCUSSION

Caries diagnosis can be considered a three-step procedure,[20] which begins with identification of the lesion (caries detection), followed by assessment of lesion severity and assessment of lesion activity. In the first study mentioned in this paper, it has been shown that, on extracted teeth, both the ICDAS caries detection systems I and II are valid and reliable for detecting caries and predicting the depth of the lesion at any coronal surface. This was expected, as the ICDAS-scoring systems have their origins in a scoring system originally devised for occlusal caries by Ekstrand and others[5,18] and has been shown in other studies to be a reliable method of occlusal caries detection.[21-22] Lesions in which discoloration due to demineralization of the dentin creates shadows beneath the enamel are usually thought to be more extensive[23-24] than lesions with a microcavity. This was the reasoning for swapping codes 3 and 4 between ICDAS I and ICDAS II, to ensure a system with codes reflecting an increased severity of lesions.

In the dental literature, the two clinical parameters that are most commonly used by dentists in their effort to diagnose caries are the visual appearance of the lesion (brown/white/cavitated) and the tactile feeling (smooth/rough) when a probe is gently run over the lesion. However, in a previous study, the combination of those two parameters alone was inadequate in determining the activity of naturally occurring lesions in a single examination.[10] The presence of dental plaque could be another predictor of lesion activity;[13,25] however, the ICDAS systems advocate the removal of plaque prior to the initial examination in order to accurately detect the lesion and so plaque cannot be used. As a result, the criteria of whether the lesion was located in a plaque stagnation area (PSA) or not (non-PSA), was suggested as a surrogate for plaque accumulation as, under normal conditions, lesion progression will occur only in plaque stagnation areas.[26]

Plaque Stagnation Areas

The occlusal surface is tricky. On an erupting premolar or a molar, the entire occlusal surface is considered to be a PSA (Table 2). In contrast, on a premolar or molar in functional occlusion, only the groove-fossae system is considered to be a PSA and only in the case that it is not too narrow or too wide. This definition is related to the facts that: 1) erupting occlusal surfaces in general accumulate significantly more plaque than fully erupted molars[25] and 2) in fissure-like parts of the groove-fossa system, whether in erupting or in fully erupted molars, the progression rate of a lesion is likely to be faster at the entrance to the fissure than in the bottom part, while in more open parts of the groove-fossa system, the progression rate is equally fast at the entrance and in the bottom part.[27] With these factors in mind, the authors introduced the ball-ended probe with a diameter of 400 µm. Thus, if the ball-ended probe could enter the local morphology (in a fully erupted molar/premolar), it should be considered a PSA, while, if the probe could not enter the local morphology because it is too narrow or too wide (no depth), it should be considered a non-PSA (Table 2).

In Table 2, the authors have also defined what is regarded as natural plaque stagnation areas in relation to smooth tooth surfaces based upon the findings of Thylstrup and Fejerskov[28] and when a cavitated lesion is considered to be a PSA or a non-PSA.

Tactile Criteria

The tactile criteria rough/soft versus smooth/hard (Table 3) that is to be used in caries activity assessment are well established in the literature.[4,9] In the ICDAS system, using periodontal probes is advocated in order to avoid traumatic defects in the enamel as a result of the incorrect use of sharp probes or explorers.[6] However, it might be argued that sharp probes and explorers may detect roughness and softness due to caries more accurately than ball-ended probes. This is an issue that should be addressed more carefully in the future.

The Validation Criteria

In this study, the impression material Clinpro Cario Diagnosis Full Arch Lactic Acid Locator was used as construct validity, as it has been shown to measure lactic acid production in plaque.[16] The impression material consists of a powder, which is mixed with an activator in order to set. It also contains a sugar solution, which the microorganisms metabolize during the three minutes that it takes for the material to set. Fermentation of the sugar and production of lactic acid by oral microorganisms is almost immediate,[17] and the result is an increasing fraction of lactic acid production. The lactic acid sets off an indicator reaction within the impression material, turning it blue in the corresponding area.

From the literature, it is known that the critical pH value at which enamel dissolves is around 5.5 and below. Study 2 showed that the Clinpro material is able to detect those cases where the pH is below 5.5; however, there are a certain number of false positive signals, because signals are also seen when the pH was between 5.5 and 5.8, resulting in a lower specificity of 0.67. However, when the sensitivity and specificity are added together, the total is 1.63. This is in the order of magnitude regarded as acceptable for a diagnostic test.[29] From this *in situ* study, it is reasonable to suggest that the ClinPro impression material is suitable as a construct validity method.

During the clinical examination in Bogota, the children's teeth were cleaned to allow accurate caries detection. Therefore, the impressions were taken about a week later to allow plaque to accumulate, a method used previously.[10] A week was thought to be an adequate length of time to let plaque re-establish in a state reflecting the routine oral hygiene level and diet of each individual. In this study, the authors decided to calculate the predictive power only based on the visible lesions. If no lactic acid producing plaque developed over a week's time, it is likely that plaque control in that region was adequate and is unlikely that the lesion was active. Similarly, if a carious lesion that was cleaned thoroughly one week prior was again covered in a lactic acid producing biofilm, it is likely that that lesion was active. A stronger proof would have been obtained if multiple impressions were taken over a period of time; however, this would have been unacceptable for the children.

The Reliability of the Clinical Parameters

In the clinical study (study 3), it was possible to maintain high reproducibility related to the scores in the ICDAS scoring system. Reproducibility related to the two other parameters was also adequate, in particular, when reproducibility was expressed as a percent agreement. Percent agreement was included in this study, because it is nearly impossible to get acceptable Kappa-values when there are only two possibilities, as is the case with plaque stagnation area and tactile feeling.

The Caries Activity Scoring Systems

All the data in this study were nominal and binary, with the exception of visual appearance. Ideally, it would have been beneficial if a predictive power could have been given to each subclass in the three clinical parameters as to whether it was weak, moderate or strong. Logistic regression analyses could therefore not be used, as one or more subclasses could be of no influence due to colinearity between the parameters (such as cavitation and softness when probed). Instead, the predictive powers of each parameter and subclass in predicting an active lesion were expressed as a simple percent agreement, with the signal in the impression material.

During development of the point system, the authors tried other divisions of the percentage scale, for example, into 3(33%), 5(20%), 6(17%) and 7(14%) parts, which resulted in other points. However, only minor differences among the four-point system and the others concerning specificity and sensitivity values were obtained.

Internal analyses disclosed that there are significant clinical consequences to choosing different cut-off points. Table 7 shows all the sub-classification permutations for the three clinical parameters, the corresponding scores and the cumulative scores that are possible based on the 4-point scoring system. The relevant cut-off points were either a cumulative score 7 (Spec+Sens = 1.66) or a cumulative score 8 (Spec+Sens = 1.67) to differentiate between active and inactive lesions. However, only the cumulative score 8 will allow all active or inactive decisions to be made on the extreme ends of the carious process; that is, a brown spot lesion can be classified as active (8 points, Table 7) and a cavitated lesion as inactive (7 points, Table 7).

Influence of Multiple Lesions From the Individual

In this study, more than one lesion from each participant was included in the analysis, which posed a statistical problem. In order to see if this had any influence, one lesion per participant (n=26) was randomly selected for further analyses. The area under the new ROC-curve did not differ from that prepared from the 123 lesions. It can therefore be concluded that there was no significant individual participant influence. This fits well with clinical experience, as within the same dentition there can be both arrested and active lesions.

Clinical Perspectives

Accurate diagnosis is essential when choosing the appropriate management strategy, which offers the best prognosis.[20] This study shows that, with a high level of certainty, lesions can be assessed as active or arrested. Active lesions always require management, which can be either non-operative/preventive or operative. The authors suggest that the appropriate treatment for active lesions should be related to the depth/severity of the lesions assessed, for example, by the ICDAS II detection system. Thus, the active lesions with detection scores 1 and 2 (superficial lesions, Table 1) require non-operative/preventive treatment, including sealants, while active lesions with detection scores 4-6 (profound lesions, Table 4) require operative treatment. Table 4 shows that some microcavitated lesions

Table 7: *Shows the possibilities when combining the three clinical parameters. The points are added up and the decision whether the lesion is arrested or active is made based on the selected threshold. The combined specificity and sensitivity is given.*

Visual Appearance	**Plaque Stagnation**	**Tactile Sensation**	**Sum VPT**	**Threshold >6 points 1.66**	**Threshold >7 points 1.67**
A) Brown spot 1	No 1	No 2	4	Arrested	Arrested
A) Brown spot 1	Yes 3	No 2	6	Arrested	Arrested
A) Brown spot 1	No 1	Yes 4	6	Arrested	Arrested
A) Brown spot 1	Yes 3	Yes 4	8	Active	Active
B) White spot 3	No 1	No 2	6	Arrested	Arrested
B) White spot 3	Yes 3	No 2	8	Active	Active
B) White spot 3	No 1	Yes 4	8	Active	Active
B) White spot 3	Yes 3	Yes 4	10	Active	Active
C) Shadow/cavitation 4	No 1	No 2	7	Active	Arrested
C) Shadow/cavitation 4	Yes 3	No 2	9	Active	Active
C) Shadow/cavitation 4	No 1	Yes 4	9	Active	Active
C) Shadow/cavitation 4	Yes 3	Yes 4	11	Active	Active

(code 3) (4 out of 13) are relatively shallow histologically and, based on previous experience, are likely to be minimally infected.[30] Such active lesions could be treated preventively with improved oral hygiene or fissure sealant; however, the remaining microcavitated lesions were deeper (69%) and would require operative treatment. For teeth with active ICDAS II scores of 3, it is important to use supplemental diagnostic tools, such as bitewing radiographs, to decide which teeth should be restored operatively.[30]

Final Remarks

In the clinical study performed in Bogota, the same sample population was used both to determine the scoring systems and test them. It is also important to understand that this study was undertaken on children from a country where children are recognized as having a relatively high caries risk. The results obtained in this study may therefore not be the same as those conducted, for example, in Scandinavia, where children are recognized as having a low risk of getting caries and having a lower caries progression rate. Studies evaluating the accuracy and reproducibility of the three clinical parameters in assessing caries activity, therefore, need to be carried out in different populations with different caries risk. In addition, in the clinical study portion of this paper, the recordings were done by only one investigator, but a well-trained one. Studies looking into inter-examiner reproducibility in the clinic also need to be carried out.

CONCLUSIONS

This study indicates that it is possible to:

1) predict coronal lesion depth correctly.
2) assess the activity of primary coronal caries lesions accurately by using the combined knowledge obtained from visual appearance, location of the lesion and tactile sensation during probing.

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