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Research Article

In-Vivo Performance of the CarieScan Pro Device for Detection of Occlusal Dentine Lesions

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Abstract. Objective: The aim of this study was to evaluate the in-vivo performance of the CarieScan Pro (CS) device based on AC Impedance Spectroscopy technology (ACIST) on occlusal surfaces. Subjects and Methods: The ethics committee approved the study and the participants gave informed consent. The study included 144 unrestored permanent molars from 24 patients. The occlusal surfaces of the teeth were examined visually using ICDAS criteria. Then CarieScan measurements were performed. The actual depth of the lesions was assessed using radiographs and/or clinically by opening the lesion when appropriate. Correlation between all methods was assessed using Spearman's rank correlation coefficient (r_s). Sensitivity (SE) and specificity (SP) were calculated at the D3- (dentine caries) diagnostic threshold and the area under the ROC curve (AUC) was assessed. Results: Significant positive correlation was found between ICDAS, CS measurements and the reference standard (r_s 0.37–0.72, $P<0.0001$). The AUC for ICDAS and CS were 0.93 and 0.84, respectively. Sensitivity/specificity for ICDAS and CS were 72.0%/96.6% and 68.0%/90.8%, respectively. Comparison of the ROC curves showed no significant difference between the ICDAS and CarieScan Pro performance ($P = 0.129$). Conclusion: Both methods showed good diagnostic performance in detection of dentine caries on occlusal surfaces.

Keywords: Occlusal caries; dentine caries; detection; in-vivo study; AC Impedance Spectroscopy technology

1. Introduction

Even though a distinct decline in caries has been observed in industrial countries in the course of recent decades [1, 2], caries detection is still one of dentists' main tasks. Its significance and the demands placed upon it have even grown as the focus has shifted from a type of dentistry primarily concerned with repair to a preventive approach involving minimally invasive dentistry. Along with the increased attention paid to patient-related factors, such as age, general condition, eating habits, etc. in determining the individual risk of caries, a large number of detection systems have also been developed in years past to support caries detection and thus also in deciding on a therapy. This includes not only refined and modified visual methods, but also a variety of instrument-based procedures. In addition, it is important to note that the distribution of carious lesions turns out differently in relation to individual tooth surfaces. Studies show that in the course of the general decline in caries, the proportion of carious lesions has often been concentrated on the occlusal surfaces of the teeth [3, 4]. Risk-oriented caries prevention assumes that a detection system is used which enables both early detection of initial lesions, as well as caries monitoring. The well-established ICDAS ("International Caries Detection and Assessment System") visual caries detection system enables lesions at various stages to be clinically detected [5]. Besides the score of "0" (caries free), six different stages of caries occurrence are registered. This method exhibits good reproducibility and a clinically acceptable specificity and sensitivity to the detection of occlusal caries [6].

As far as instrument-based methods are concerned, the so-called "Alternating Current Impedance Spectroscopy Technique- (ACIST)" is a current non-invasive method of caries detection. The principle is based on the fact that intact enamel works as a good insulator in an electrical circuit owing to its chemical composition [7, 8]. This phenomenon changes when the hard tooth structure is destroyed by caries, enabling the extent of demineralization of the enamel or dentine to be determined and quantified by means of ACIST. A currently available commercial system for detection on smooth surfaces and fissures based on ACIST is the CarieScan Pro device (CarieScan Ltd., Dundee, UK). During the examination, alternating currents at several frequencies are sent through the tooth and a spectrum of impedance points are created. The result of the measurement is analyzed by the software installed into the device and displayed both numerically on a scale from 0 to 100 as well as by way of color coding (from green to red). The higher the numerical value, the more serious is the spread of the lesion. In-vitro, it was possible to ascertain high levels of 92.5% for both the sensitivity and specificity of the method on fissures and smooth surfaces [9]. The available data on clinical studies is at present minimal. For instance, *Teo et al.* [10] studied the diagnostic performance of CS in-vivo and in-vitro, yet only on teeth of the primary teeth. Since there are at present no published data regarding the clinical use of ACIST on permanent dentition, this study aimed to determine the diagnostic performance of CS in detecting dentine lesions on occlusal surfaces of posterior teeth.

2. Materials and Methods

2.1. Patient selection and visual examination. The study was independently reviewed and approved by the ethics committee of the Medical faculty of Philipps-University, Marburg (approval number 191/10) and was conducted in accordance with the ethical standards laid down in the Declaration of Helsinki. Prior to the study, a power calculation was performed using G*Power 3 [11]. In expectation of a medium correlation, $\alpha = 0.05$ and a power of 0.9, a sample size of 112 teeth was calculated. A dropout rate of 15% was added to the required sample size. At least 129 teeth had to be included in the study. The patients were selected sequentially from regular dental screenings. Subjects were at least 18 years of age and gave their informed, written consent prior to their inclusion in the study. Only posterior teeth without restoration were included for examination in this study. ICDAS scores for the occlusal surfaces were obtained after the teeth were cleaned and air-dried using a triplex syringe by two experienced examiners (A J-M and SMC K) and consensus decision was made for each investigation site. The sites were recorded as [12]: 0 = sound; 1 = first visible sign of non-cavitated lesion seen only when the tooth is dry; 2 = visible non-cavitated lesion seen when wet and dry; 3 = microcavitation in enamel; Code 4 = non-cavitated lesion extending into dentine seen as an undermining shadow; Code 5 = small cavitated lesion with visible dentine: less than 50% of surface; Code 6 = large cavitated lesion with visible dentine: more than 50% of surface.

2.2. Assessments with the CarieScan Pro (CS) device. The CarieScan measurements were performed by one examiner (SMC K). In order to calculate intra-examiner reproducibility of the impedance measurements, the occlusal surface of 30 extracted teeth were examined twice using the CS prior to the in-vivo study following manufacturer´s instructions. The intra-class correlation coefficient (ICC) was 0.85 (95% confidence interval 0.71–0.92).

For the main study, measurements were taken at each selected occlusal surface and the CS value was recorded for the site where the visual examination was performed. Each tooth was dried for 3-5 seconds at moderate pressure prior to the measurements. One examiner performed all CS measurements. Lesion extent and depth was determined using the CS cut-offs recommended by the manufacturer: 0 = likelihood of being sound; 1–50 = early stage of enamel lesion; 51–90 = deep enamel lesion; 91–99 = possibility of established decay extending through the enamel and into superficial dentine; 100 = likelihood of established dentine caries

2.3. Determination of the "reference standard". The information on the depth of the lesion was normally ascertained by X-ray and/or after excavating the tooth [13, 14]. When radiographs were available (< 6 months) they were examined for the presence or absence of caries. If justified by individual caries risk, new bitewing radiographs were taken. For treatment decision, not only the extent but also individual factors (e.g., caries risk, activity of the lesion) were taken into account. This type of procedure corresponds to currently effective recommendations [14–16]. When ICDAS code 0 was assessed, the surface was assessed as sound (D0) and no new radiographs were taken. ICDAS codes 1–2 were assessed as enamel lesions (D1) and radiographs were evaluated in addition, depending on availability. ICDAS codes 3–6 (D3) were assessed as dentine lesions [6] and radiographs were inspected for lesion depth. To determine the depth of the lesions, the surfaces were opened with rotating instruments. All cavities were restored using permanent fillings following the usual clinical procedures.

2.4. Statistical analysis. Statistical analysis was performed using SPSS, Version 15.0 and MedCalc, Version 12.7.5. Correlation among visual scores, impedance measurements

Table 1: Cross tabulation of ICDAS and CarieScan Pro findings (CS).

CS value	ICDAS code						N (%)
	0	1	2	3	4	5	
0	1	0	2	0	0	0	3 (2.1)
1-50	20	33	13	1	2	0	69 (47.9)
51-90	6	15	16	4	2	0	43 (29.9)
91-99	0	3	2	2	0	0	7 (4.8)
100	3	3	5	8	1	2	22 (15.3)
N (%)	30(20.8)	54(37.5)	38(26.4)	15(10.4)	5(3.5)	2(1.4)	144 (100)

and the reference standard was assessed using Spearman's rank correlation coefficient (r_s). The significance level was set at $\alpha = 0.05$. Receiver Operating Characteristic (ROC) curves and the area under the curve (AUC) were calculated. Furthermore, sensitivity (SE), specificity (SP), positive and negative predictive values (ppv, npv) were calculated at the level of dentine caries.

3. Results

For this clinical study, 24 subjects were examined, of whom 9 were male and 15 were female. The average age was 26.7 years (21.4–34.4 years). A total of 144 teeth were examined. The distribution of the ICDAS scores is presented in Table 1.

Of the teeth examined, 20.8% exhibited no visible sign of caries (ICDAS code 0). Dentine caries was detected in 15.3% of the teeth (ICDAS code > 2), although there was no case of ICDAS code 6 among the examined cohorts. The total number of occlusal surfaces with radiographic examination was 76 (52.3%).

Significant positive correlations were found between all methods ($P < 0.0001$, two-tailed). The correlation of the visual method to the CS measurements and to the reference standard was 0.37 and 0.72, respectively. The CS values and the reference standard exhibited a moderate correlation of 0.44.

Cross tabulation of visual and CS findings with the reference standard is presented in Table 2. According to the reference standard, 17.4% ($n = 25$) of the teeth had dentine caries. The fissures of all surfaces with dentine lesions were opened for operative treatment.

The diagnostic accuracy (AUC, Table 3) for both methods was in a good range. The data on sensitivity and specificity show that the sensitivity to the detection of dentine was better for the ICDAS (72%) than for the CS method (68%). Comparison of the ROC curves [17] showed no significant difference between the ICDAS and CarieScan Pro performance ($P = 0.129$). ROC curves are presented in Figure 1.

In this study population, the positive predictive value was high for the visual method (81.8%) and acceptable for the CS device (60.7%, Table 3).

4. Discussion

In this study, the diagnostic performance of the CarieScan Pro in detecting occlusal dentine lesions was determined in-vivo. No validation was ascertained for enamel lesions owing to the ethical problems involved in the reference. It would not have been acceptable to take X-rays or even open every suspicious fissure to ensure the visual examination. Thus initial changes in the enamel mistakenly seen as sound in a visual examination would not be defined as such. Some authors reject operative intervention in favor of individual caries monitoring even in the case of initial dentine lesions (not radiographically representable and non-cavitated) [18]. Restorative treatment methods are said to be legitimate in the presence of a cavitation which cannot be cleaned and/or an active dentine lesion which impairs function [16].

Significant positive correlations were found between all methods ($P < 0.0001$, two-tailed). While the correlation of the ICDAS with the reference standard was highest, at 0.72, the correlation of the CS to the visual method and the reference standard was only moderate, at 0.37 and 0.44. The high level of sensitivity for the detection of dentine lesions in-vivo could not be confirmed in this study. It came out to a distinctly lower 68%, while the specificity was similarly high at 90.8%. A high, predictable diagnostic specificity has gained in importance owing to the reduced caries prevalence and slowing caries progression rate [19]. The sensitivity and specificity values for the visual detection system were 72% and 96.6%, somewhat higher than those which could be ascertained for the CS. The area under the receiver operating characteristic curve (AUC) was 0.84, denoting a sufficient to good diagnostic performance, whereas the AUC for the ICDAS was in the high range at 0.93 (Table 3). However, this difference is not statistically significant ($P = 0.129$). Hence it would be recommended to use the CS in combination with visual methods. Many authors recommend a combination of several methods to thoroughly detect occlusal caries [20–23].

The CS enables caries-related changes in the hard tooth structure to be objectively displayed to the patient. As the orientation of dentistry is increasingly shifting toward prevention, this represents a valuable aid in communicating with patients and in improving follow-ups. With the aid of the numerical lesion quantification, it is possible to first observe the teeth and undertake a remineralizing intervention in the

Table 2: Cross tabulation of ICDAS/CarieScan Pro with reference standard.

	Reference standard		
	no dentine lesions	dentine lesions	N (%)
ICDAS 0 (sound)	30	0	30 (20.8)
ICDAS 1–2 (enamel lesions)	85	7	92 (63.8)
ICDAS 3–6 (dentine lesions)	4	18	22 (15.4)
N (%)	119 (82.6)	25 (17.4)	144 (100)
CarieScan 0 (sound)	3	0	3 (2.1)
CarieScan 1–90 (enamel lesions)	104	8	112 (77.8)
CarieScan 91–100 (dentine lesions)	12	17	29 (20.1)
N (%)	119 (82.6)	25 (17.4)	144 (100)

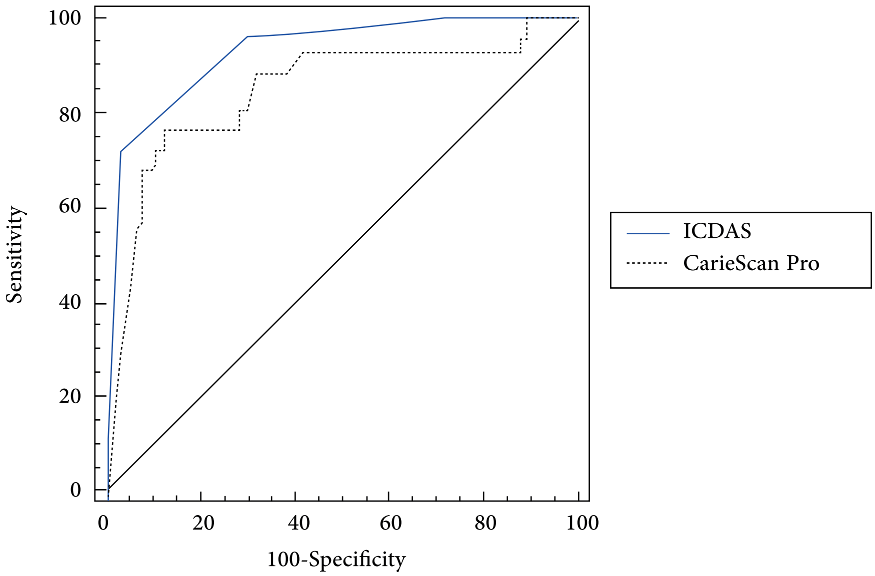

Figure 1: ROC curves for ICDAS and CS findings at the D3 diagnostic threshold (dentine caries).

sense of "monitoring,'' but to take subsequent invasive action only if a progressive carious change is detected. What is more, taking X-ray photographs requires a "justifying indication'' to be present (according to German X-ray regulations) [24]. In view of this, other methods with comparable health benefits yet involving little or no exposition to radiation should be considered.

As is well known, the positive predictive value is a parameter for estimating the validity of medical test procedures. It indicates how many persons in whom a test procedure has detected a specific disease are, in fact, diseased. In relation to our study of "caries'' as a disease, this means that the validity of the actual existence of a carious change will be low in a cohort with low caries prevalence (as in the present study). Conversely, the predictive value for detecting sound tooth surfaces as such will be relatively large. While the positive predictive value for the visual method was high, at 81.8%, the 60.7% value ascertained for the CS was in the acceptable range. This likewise supports the recommendation of using a combination of the instrument-based method with visual evaluation.

In the present study, the specificity and sensitivity were determined on the basis of the cutoff points indicated by the manufacturer. As a matter of principle, the definition of such threshold values deserves closer scrutiny. If the threshold value for a procedure is low, a relatively large number of teeth will be diagnosed as diseased. This gives rise to the risk of false positives representing healthy teeth as diseased even though they require no operative treatment. In contrast, a high threshold value will classify a large number of investigation sites as sound, but can result in false negatives, so that carious teeth are presented as sound. The choice of a low threshold would hence in practice lead to unwarranted invasive interventions on sound tooth tissue. This risk can be reduced by using a relatively high threshold, which is advisable in populations with a low risk of caries [25]. When deciding for or against invasive treatment, the practitioner must be aware that threshold values can at best serve as

Table 3: AUC, sensitivity, specificity, positive and negative predictive values for ICDAS and CarieScan Pro at the D3 diagnostic threshold (dentine caries).

Method	AUC (Standard error)	95% CI	SE (%)	SP (%)	PPV(%)	NPV (%)	Cut-off
ICDAS	0.93 (0.03)	0.87-0.96	72.0	96.6	81.8	94.3	2/3
CarieScan Pro	0.84 (0.05)	0.77-0.90	68.0	90.8	60.7	93.1	90/91

AUC = Area under the curve; CI = Confidence interval; SE = Sensitivity; SP = Specificity PPV = positive predictive value; NPV = negative predictive value

an aid to orientation and should not be used as the sole criterion. Especially when using ACIST, for instance, the age of the patients is of decisive importance to the interpretation of the results of measurement: the diameter of the dentinal tubuli decreases significantly with age through the apposition of peritubular dentine. The dentine therefore contains fewer electrically conductive electrolytes, resulting in an overall higher resistance [26, 27]. Among young patients, on the other hand, the post eruptive enamel maturation represents a measurable independent variable [8, 28, 29]. *Teo et al.* [10] examined the performance of the CS on 65 deciduous teeth, in which lesions were given a histological classification after the teeth were extracted. The specificity ascertained at the D3 level was low, at 43%, compared to a sensitivity of 95%. This result suggests that the physiological differences between deciduous teeth and permanent teeth also affect the results of measurement.

In general the shortcoming of this clinical study is the lack of a gold standard with histological validation. Hence sensitivity and specificity data should be interpreted carefully. An alternative validation procedure may be re-investigation of sound sites after a distinct time period and this should be taken into account for further studies using clinical reference standards. Another problem is that not all teeth had a radiographic examination. This could lead to potential bias since it can be assumed that the no x-ray group was less likely to have caries. According to the above mentioned “justifying indication’’ it was not indicated to take radiographs from each tooth and this may be also having led to weaker results.

In summary, it could be shown that the CS achieved good diagnostic performance in the detection of dentine caries on occlusal surfaces with respect to the limitations of the methodology in this clinical setting. Nevertheless, a decision regarding treatment options should always include visual assessment of the lesion as an essential step; additional factors, such as age and the individual’s caries risk, are likewise to be taken into account when making a diagnosis and deciding on the treatment options.

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Conflict of interest

The authors (Anahita Jablonski-Momeni and Sarah Marie Christin Klein) declare that they have no conflict of interest

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