Reliability of clinical diagnosis and DIAGNOdent™ measurement value for dental caries comparing with results of contact microradiographic examinations

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Abstract : The histopathological diagnosis cannot be performed in the dental caries, and thus, accuracy of clinical diagnosis is uncertain. The purpose of this study is to examine the reliability of clinical diagnosis by conventional methods and to examine the diagnostic variation among examiners in vitro. Visual inspections using an air syringe, probing using a dental explorer and radiographic examinations were all used for clinical diagnosis. Clinical diagnosis and final diagnosis by the contact microradiography (CMR) were compared using extracted carious teeth. DIAGNOdent™, a laser fluorescence device for caries detection was also examined as an objective method for clinical diagnosis. As a result, 81% of the clinical diagnosis matched those from the CMR diagnosis. Specificity for clinical diagnosis of four dentists ranged between 0.8 and 1.0 (C_1) and between 0.63 and 0.88 (C_2). Sensitivity ranged between 0.5 and 0.83 (C_1) and between 0.88 and 1.0 (C_2). The Kappa values varied from 0.45 to 0.66. The results of DIAGNOdent™ measurements correlated with the final diagnoses at the rate of 50%. In conclusion, inter-examiner reproducibility was not always high and clinical diagnosis seemed to vary by examiners even when common conventional methods were used. Thus, in order to provide a more accurate clinical diagnosis more investigation seems to be necessary, though 81% of clinical diagnosis matched final diagnosis. On the other hand, DIAGNOdent™ measurement value alone was not as dependable as clinical diagnosis at present.

Key Words : dental caries, clinical diagnosis, final diagnosis, contact microradiography, DIAGNOdent™

Introduction

Visual inspections using an air syringe, probing using a dental explorer and radiographic examinations are conventional methods used for making a clinical diagnosis of

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dental caries. In the case of a cyst or a tumor, histopathological diagnosis is also performed for a final diagnosis. But in the lesions of dental caries, the histopathological diagnosis cannot be performed and thus, accuracy of clinical diagnosis is uncertain. Studies which used extracted teeth have reported that the inter-examiner Kappa values were found to be 0.35 to 0.45 and 0.66 to 0.77[1-2]. They showed that clinical diagnoses do not always agree among dental examiners. In some studies, clinical diagnoses were compared with final histological diagnoses, and it was found that the rate of the agreement between both diagnoses was not necessarily high[3-5]. However, some of them were carried out using mainly sound and primary enamel carious teeth. In terms of preventive dentistry, differentiation between non-carious teeth and teeth with primary enamel caries is very important. Additionally, in the field of operative dentistry, differentiation between enamel caries and deep dentin caries is also important. To understand the extent to which clinical diagnosis by conventional methods agree with final diagnosis, or other words, to recognize the reliability of clinical diagnosis will help dental clinicians to provide better treatment. The purpose of this study is to examine the reliability of clinical diagnosis by conventional methods and to concretely examine the diagnostic differences between examiners. Clinical diagnosis by common examination and final diagnosis by contact microradiogram (CMR) were compared using extracted teeth with carious lesions. In addition, DIAGNOdent™ (KaVo, Biberach, Germany) was examined as an objective method for clinical diagnosis. The laser fluorescence device for caries detection illuminates the tooth with laser light (λ = 655nm). Altered tooth hard tissues including caries and bacteria, will fluoresce. Changes in the mineral content and porosity of the surface result in a change in the pattern of fluorescence. The nature of emitted fluorescence correlates with the degree of demineralization in the tooth and can be quantified. A numerical value from 0 to 99 are assigned to the degree of fluorescence, which is used as an indicator of the extent of dental caries.

Materials and Methods

Extracted human third molars (n=15, stored in 10% formalin) were randomly selected and used for the study. The teeth were first thoroughly rinsed with water and then cleaned with a brush-cone without toothpaste. Sixteen sample regions on pits and fissures were selected to be diagnosed, and then numbered from 1 to 16. Dental caries detection using DIAGNOdent™, clinical diagnoses by four dental clinicians and final diagnoses by CMR were each performed in the sample regions for comparison.

Measurements using DIAGNOdent™

DIAGNOdent™ measurement was carried out prior to clinical diagnosis to avoid damage to the sample by explorer. A conical probe for pits and fissures was used in accordance with the manufacturer's instructions. An air syringe was used to dry the teeth. The standard value for each individual tooth was calibrated before each measurement by measuring a region of smooth intact enamel. The sample regions were carefully scanned for 20 seconds, while rotating and moving the probe in various directions. This was repeated 3 times. All measurements were performed by the same examiner. The highest measurement value from

Table 1. Cut-off points for DIAGNOdent™ measurement.

Value	Diagnosis	Condition
0-10	C_0	healthy tooth structure
11-20	C_1	outer half enamel caries
21-30	C_1	inner half enamel caries
31-99	C_2	dentinal caries

each sample region was registered as the representative value. Cut-off values listed in the manufacturer's instruction manual for DIAGNOdent™ were used for diagnosis (Table 1).

Clinical diagnosis

After DIAGNOdent™ measurements were completed, clinical diagnoses of teeth were performed by four examiners who each have 5 to 30 years of experience as dental clinicians. They were not informed of the results of DIAGNOdent™ measurements to exclude bias. The DIAGNOdent™ examiner did not take part in clinical diagnosis. Dental X-ray pictures of all sample teeth were taken from the buccal side using the bisecting-angle technique employed in routine clinical methods. Dental films were used at 60kV, 10mA, and with an exposure time of 0.1s. Visual inspections using an air syringe, probing using a dental explorer and dental radiographs were all used for clinical diagnosis. Diagnostic criteria are shown in Table 2. In cases where all of the clinical diagnoses are not in agreement, the result where at least three of the dentists gave the same diagnosis was employed.

Final diagnosis by CMR

Following the clinical diagnosis, the sample teeth were dehydrated in graded ethanol and then, embedded in polyester resin (Rigolac; Maruto Co., Ltd, Tokyo, Japan). Ground sections, 100㎛ in thickness, were made and CMRs using X-ray films (Konica Minolta High Precision Plate) were taken by a soft X-ray generator (SOFRON SRO-M50; Sofron Co., Ltd, Tokyo, Japan) under the condition of 13kV, 3 ㎃. The focus to film distance was 50㎜ and an exposure time was 20 min. The films were developed with Kodak D-19 for 5 min at 20℃, rinsed with tap water and then fixed with Fujifix for 5 min at 20℃. Final diagnoses were made after observing the CMR pictures, in detail, under a microscope[6]. Criteria for diagnosis are shown in Table 3. Specificity, sensitivity and the kappa statistics were calculated in order to evaluate the

Table 2. Clinical diagnosis criteria.

Score	Criteria
C_0	neither visible caries nor defect of tooth surface
C_1	caries restricted to the enamel
C_2	caries extending to the dentin without dental pulp involvement
C_3	caries extending to the dental pulp

Table 3. Criteria for final diagnosis by CMR.

Score	Criteria
C_0	no rediolucency
C_1	radiolucency restricted to the enamel
C_2	radiolucency extending to the dentin without dental pulp involvement
C_3	radiolucency extending to the dental pulp

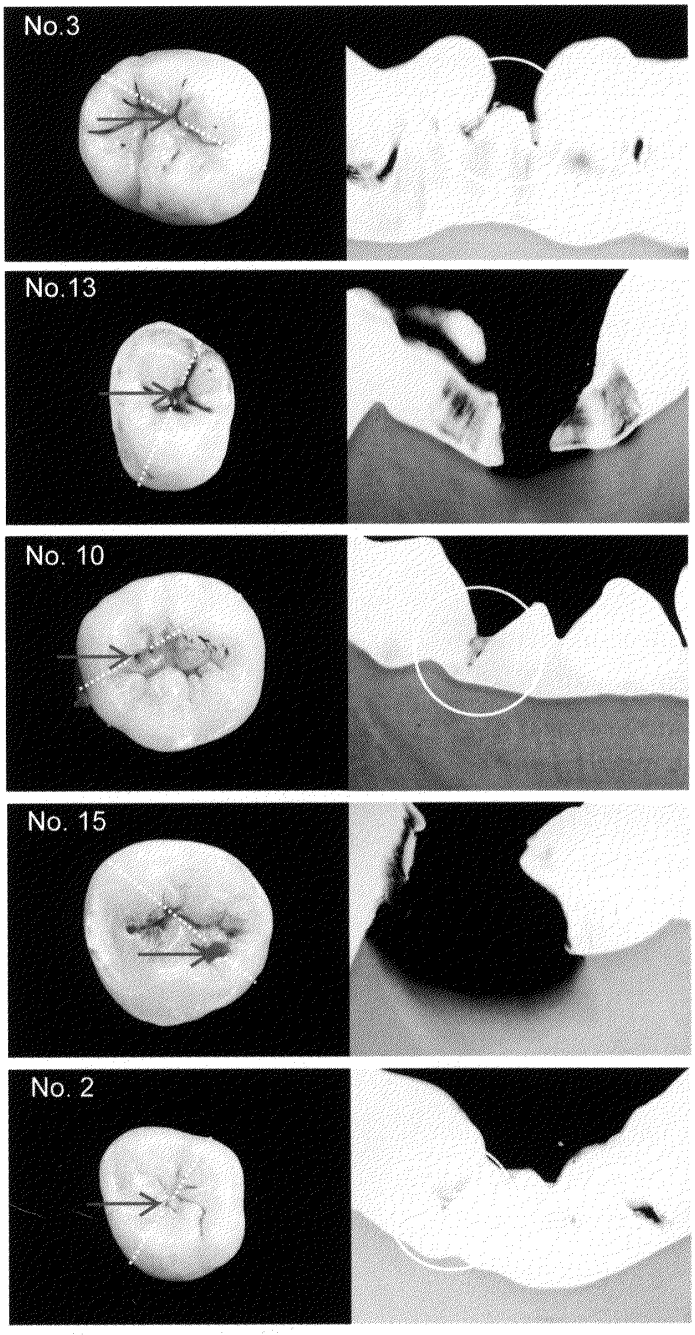

Fig. 1. Macroscopic pictures of examined teeth and contact microradiograms(CMR).
The broken lines show the direction of ground sections.
The arrows show points used for diagnosis of both clinical and CMR examinations and DIAGNOdent™ measurement.
Each diagnosis was performed using diagnostic criteria shown in Table 1, 2 and 3.
No.3, clinical diagnosis ; C_1, final diagnosis ; C_1, DIAGNOdent™ measurement value ; 45, Both clinical diagnosis and DIAGNOdent™ value matched final diagnosis.
No.13, clinical diagnosis ; C_2, final diagnosis ; C_2, DIAGNOdent™ measurement value ; 83, Both clinical diagnosis and DIAGNOdent™ value matched final diagnosis.
No.10, clinical diagnosis ; C_2, final diagnosis ; C_1, DIAGNOdent™ measurement value ; 32, Only clinical diagnosis did not match final diagnosis.
No.15, clinical diagnosis ; C_2, final diagnosis ; C_2, DIAGNOdent™ measurement value ; 14, Only DIAGNOdent™ value did not match final diagnosis.
No.2, clinical diagnosis ; C_0, final diagnosis ; C_0, DIAGNOdent™ measurement value ; 99, DIAGNOdent™ value was outlier.

inter-examiner reproducibility of the four dentists.

Results

The results of DIAGNOdent™ measurements, clinical diagnoses and final diagnoses are shown in Table 4. Figure 1 shows macroscopic view of examined teeth and the CMR pictures. Final diagnosis by CMR showed that there were two cases of C_0, six C_1, eight C_2 and no C_3. On the other hand, clinical diagnosis by the four dentists showed there were one case of C_0, five C_1, ten C_2 and no C_3. 81% of the results from the clinical diagnosis matched those from the final diagnosis. Specificity and sensitivity for C_1 and C_2 are given in Table 5. Specificity for clinical diagnosis of four dentists ranged 0.80 to 1.00 (C_1) and 0.63 to 0.88 (C_2). Sensitivity ranged 0.50 to 0.83 (C_1) and 0.88 to 1.00 (C_2). The results of DIAGNOdent™ measurements correlated with the final diagnoses at the rate of 50%. Although all diagnoses were performed very carefully, the result of sample No.2 was an outlier. It showed the highest DIAGNOdent™ value of 99, however the clin-

Table 4. Results of each diagnosis.
▲Contradictory results with final diagnosis.

Sample No.	Dentist (1)	Dentist (2)	Dentist (3)	Dentist (4)	Clinical diagnosis	The ratio of agreement	Final diagnosis	Restorative treatment	DIAGNOdent™ Measurement	Restorative treatment
No.1	C_1	▲C_2	▲C_2	▲C_2	▲C_2	3 / 4	C_1	○	45	○
No.2	C_0	▲C_1	C_0	C_0	C_0	3 / 4	C_0	×	99	▲○
No.3	▲C_0	C_1	C_1	C_1	C_1	3 / 4	C_1	○	45	○
No.4	C_1	C_1	C_1	C_1	C_1	4 / 4	C_1	○	30	▲×
No.5	C_1	C_1	▲C_2	C_1	C_1	3 / 4	C_1	○	16	▲×
No.6	C_1	C_1	C_1	C_1	C_1	4 / 4	C_1	○	16	▲×
No.7	C_2	C_2	C_2	C_2	C_2	4 / 4	C_2	○	45	○
No.8	C_2	C_2	C_2	C_2	C_2	4 / 4	C_2	○	22	▲×
No.9	C_2	C_2	C_2	C_2	C_2	4 / 4	C_2	○	9	▲×
No.10	▲C_2	▲C_2	▲C_2	C_1	▲C_2	3 / 4	C_1	○	32	○
No.11	C_2	▲C_3	C_2	C_2	C_2	3 / 4	C_2	○	37	○
No.12	C_2	C_2	C_2	C_2	C_2	4 / 4	C_2	○	99	○
No.13	▲C_1	C_2	C_2	C_2	C_2	3 / 4	C_2	○	83	○
No.14	▲C_1	▲C_1	C_0	▲C_1	▲C_1	3 / 4	C_0	×	37	▲○
No.15	C_2	C_2	C_2	C_2	C_2	4 / 4	C_2	○	14	▲×
No.16	C_2	C_2	C_2	C_2	C_2	4 / 4	C_2	○	34	○
Accuracy	0.75	0.69	0.81	0.88	0.81	-	-	-	-	0.5

Table 5. Specificity and sensitivity.

	Specificity		Sensitivity	
	C_1	C_2	C_1	C_2
Dentist (1)	0.80	0.88	0.67	0.88
Dentist (2)	0.80	0.75	0.67	0.88
Dentist (3)	1.00	0.63	0.50	1.00
Dentist (4)	0.90	0.88	0.83	1.00
Clinical Diagnosis	0.90	0.75	0.67	1.00

Table 6. Kappa values for inter-examiner reproducibility of clinical diagnosis using conventional methods.

Dentists	Kappa value
(1) vs (2)	0.46
(1) vs (3)	0.45
(1) vs (4)	0.56
(2) vs (3)	0.54
(2) vs (4)	0.66
(3) vs (4)	0.65

ical and final diagnosis both showed no caries. As for sample No.3 and No.13, both clinical diagnosis and DIAGNOdent™ measurement agreed with final diagnosis. As for sample No.10, only the clinical diagnosis did not agree with the final diagnosis. As for sample No.14, only DIAGNOdent™ measurement did not match final diagnosis. The results of inter-examiner reproducibility is shown in Table 6. The Kappa value of this study was 0.45 to 0.66.

Discussion

In this study, three diagnostic procedures (visual inspection, probing, and radiographic examination) were used to simulate routine clinical examination. Compared to final diagnosis by CMR, the correlation between clinical diagnosis and final diagnosis was 81%. This indicates that nearly 20% of the tested cases were not properly diagnosed. The results show the difficulties of clinical diagnosis of occlusal carious lesion. As microstructures are difficult to discern from dental X-ray pictures, detecting a small caries can be challenging. Since pits and fissures on molars are complicated and internal structure is not visible, visual inspection is subjective[7]. Although probing using a dental explorer is necessary to investigate inside the pits and fissures in detail, sometime dentists are reluctant to use it because the explorer could possibly break the delicate surface of the carious lesions[8]. Penning et al.[9-12] investigated effectiveness of probing for fissure caries. The effectiveness of probing was compared with final diagnosis using X-ray images of sample sections, and it was found that probing was unreliable for the diagnosis of fissure caries. Out of the 16 clinical diagnoses, eight cases were matched by all four dentists, and also correlated with final diagnosis(100%). The other eight clinical diagnoses were agreed upon by three dentists, and out of those diagnoses, five correlated with the final diagnosis (62.5%). Although the most experienced dental clinician (dentist(4)) scored the highest specificity for C_2 and sensitivity for C_1 and C_2, 2 cases in 16 did not matched final diagnosis. The examined teeth where clinical diagnosis did not match the final diagnosis, were diagnosed as more severe caries than they actually were. Sample No.1 and No.10 were clinically diagnosed as C_2, however the caries did not extend to the dentin on CMR. Information from clinical inspection is too limited to recognize the condition of caries in detail. In order to evaluate the inter-examiner reproducibility of the four dentists, the Kappa statistics were calculated. The Kappa value of this study was found to be 0.45 to 0.66. Manji et al[1]. obtained inter-examiner Kappa values of 0.66 to 0.77 using criteria of 1) sound, 2) enamel lesion and 3) others. Rosén et al.[2] found Kappa values of 0.35 to 0.45 for inter-examiner tests using clinical caries diagnosis for coronal surface using of 1) sound enamel, 2) initial active caries, 3) initial inactive caries, 4) manifest active caries and 5) manifest inactive caries criteria. Although a comparison of clinical diagnosis with final diagnosis based on histology was not performed in these studies, variation and difficulty of clinical diagnosis was confirmed. It is not always because of the inexperience of dentists or matter of ability, every clinical diagnosis could potentially include unreliable factors which can compromise the effectiveness of conventional method. To compensate for the unreliable factors in conventional clinical diagnosis, an

objective diagnostic system with high reproducibility has been anticipated. The effectiveness and reproducibility of DIAGNOdent™ have been reported in many papers[13-19]. In this study, the device was calibrated on smooth intact enamel before each measurement. The probe was rotated and moved carefully in various directions to detect caries while being measured by the examiner. The agreement between DIAGNOdent™ and final diagnosis was 50%. A clear explanation for the low rate of agreement between DIAGNOdent™ measurements and final diagnoses was not found. Clinical utilization of DIAGNOdent™ on patients would be more difficult because moving and rotating the probe would not be easy inside the mouth, especially on molars. However, its non-invasive method using laser fluorescence is useful for uncooperative children and patients who cannot receive an X-ray examination due to pregnancy or physical disabilities etc. To make DIAGNOdent™ measurements easier and more reliable to use, modifications of the devise such as a smaller probe with a thin tip to detect caries on pits and fissures are anticipated.

Conclusions

In conclusion, the results of our study seem to indicate that :

(1)19% of clinical diagnoses by conventional methods did not correlate with the final diagnoses.

(2)Inter-examiner reproducibility was not always high and clinical diagnosis varied by examiners even when common conventional methods were used.

(3)As undetectable factors are included in clinical caries diagnosis, dentists should take this into consideration when treating caries.

(4)DIAGNOdent™ measurement value alone was not as dependable as clinical diagnosis at present.

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齲蝕の臨床診断とDIAGNOdent™計測値の信頼性に関するコンタクトマイクロラジオグラムとの比較研究

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抄録：齲蝕の治療を行うにあたり，齲蝕部位の病理組織学的診断を行うことは実際に不可能である。そのため，実際に行われている臨床診断の精度は明らかでない。本研究の目的は，ふだん行われている診査方法による臨床診断の信頼性，および術者間における診断の変動についてin vitroで調べることである。臨床診断にはエアーシリンジを用いた視診，探針による触診，それにエックス線診が使われた。試験には抜去歯が用いられ，臨床診断とコンタクトマイクロラジオグラム（CMR）による最終診断が比較された。レーザー型齲蝕検出装置であるDIAGNOdent™も客観的に臨床診断を行う方法として検討を行った。その結果，臨床診断のうち81%がCMRによる最終診断と一致した。4名の歯科医師の特異度はC_1で0.8から1.0，C_2で0.63から0.88だった。敏感度はC_1で0.5から0.83，C_2で0.88から1.0だった。Kappa係数は0.45から0.66だった。DIAGNOdent™と最終診断の一致率は50%だった。結論として，術者間の再現性は必ずしも高くはなく，共通の診断方法を使った場合でも術者によって臨床診断は変化するように思われた。したがって，臨床診断と最終診断は81%が一致したが，より正確な臨床診断を行うためにはさらなる研究が必要と思われる。一方，単独のDIAGNOdent™計測値は現在のところ，臨床診断ほどには信頼できないものだった。

キーワード：歯科齲蝕，臨床診断，最終診断，コンタクト　マイクロラジオグラフィー，DIAGNOdent™