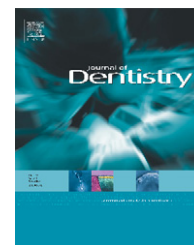


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The intra/inter-examiner reproducibility of the new DIAGNOdent Pen on occlusal sites

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ABSTRACT

Objective: This *in vitro* study on occlusal sites aimed to assess the intra/inter-examiner reproducibility of the new DIAGNOdent Pen (KaVo, Biberach, Germany) and to prove the assumption that its handling is easy to learn by dental students.

Methods: Two hundred and forty-one sites of 90 occlusal non-cavitated molar surfaces were investigated twice by 2 dentists and 2 undergraduate students with the DIAGNOdent Pen according to manufacturer's instructions. Intra/inter-examiner reproducibility was assessed calculating intra-class correlation coefficients (ICCs) and the range of the 95% limits of agreement by Bland and Altman.

Results: Intra-examiner reproducibility revealed excellent ICCs (0.84–0.92); but the range amounted to 41.2–59.1, which indicate a wide measuring range. The inter-examiner reproducibility using all measurements had to be proved as excellent (ICC 0.84); the range was found in the same order of magnitude as mentioned above (53.2). When measurements were categorised according to treatment related cut-offs a good inter-examiner reproducibility was detected in the interval of <30 (ICC 0.70); an excellent ICC were registered for the interval >30 (ICC 0.51). For both intervals the range values (<30: range 32.3 and >30: range 67.7) exceeded a deviation limit of $\pm 20\%$. Both students tended to measure slightly more precise compared to the dentists.

Conclusions: This study revealed a wide measuring range of DIAGNOdent Pen readings. Since there were no differences between dentists and students it can be used as adjunct tool by undergraduates as well. Nevertheless, based on the registered reproducibility the DIAGNOdent Pen should be used additionally to visual inspection and dental radiographs.

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1. Introduction

The laser fluorescence device DIAGNOdent 2095 (KaVo, Biberach, Germany) intended for quantification of occlusal caries was introduced to the dental market in 1998. Since then, various reproducibility data for laser fluorescence measurements have been published. While most of them attested a good to excellent reproducibility of DD2095 measurements,¹ others found unsatisfactory results.² In 2005 the DIAGNOdent

Pen (DIAGNOdent 2190, KaVo, Biberach, Germany), which is reduced in size and designed as a handpiece became commercially available. As it is an essential prerequisite for each dentist measuring consistent results over repeated tests of the same site under identical conditions and as there are only preliminary intra-examiner reproducibility data³ and no inter-examiner results of the DIAGNOdent Pen available so far, this *in vitro* study aimed to analyse the intra/inter-examiner reproducibility on occlusal sites. Furthermore, it was the aim

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to compare the reproducibility exemplary for undergraduate students and experienced dentists to prove the assumption that the handling of the device is easy to learn.

2. Materials and methods

A total of 90 non-cavitated third molars selected from a pool of teeth that had been extracted for surgical or orthodontic reasons constituted the study material. All teeth had been extracted by dental practitioners in Germany. Prior to extraction an informed consent of the patients regarding the anonymous scientific use of the donated tooth material was obtained. Only molars without sealants, fillings, occlusal cavitations, approximal and/or buccal/lingual caries lesions, stains and/or developmental disorders were included. After gross debris had been removed by hand instruments, the teeth were cleaned with rotating brushes and an air polisher (PROPHYflex, KaVo, Biberach, Germany). To prevent any bacterial growth, the specimens were submerged in physiological saline with 0.02% sodium azide.² Each tooth was stored in a separate receptacle under room temperature.

Digital photographs were taken and printouts of all 90 molars were made to mark and number exactly each occlusal measurement site. The selection of all sites was done after visual inspection and careful laser fluorescence measuring 2 weeks before the beginning of the measuring cycles. Altogether 241 occlusal sites (no pits) had to be measured twice within an interval of 1 week by four examiners (two experienced dentists/two undergraduate students) to determine the intra/inter-examiner reproducibility. Hence, a total of 1928 readings were recorded with the fissure tip of the DIAGNOdent Pen. Before each measurement cycle the DIAGNOdent Pen was calibrated with the appropriate ceramic standard according to the manufacturer's instructions. The correct calibration was daily checked after finishing the measurements; no deviations greater than ± 3 DIAGNOdent units were registered during the study period. A 2-h theoretical and practical audit was carried out before beginning of this study.

The *in vitro* measurement of each occlusal site consisted of a brief air drying for about 5 s with the air syringe of the dental unit. Following the registration of the inherent fluorescence value on the mesio-buccal cusp of each tooth (zero value) the fissure probe for occlusal surfaces was placed on the measurement site and slightly tilted. Circular movements were performed along the entire fissure pattern. The max-

imum reading for each site was recorded. All examiners were encouraged to re-measure carefully sites with doubtful readings.

The statistical analysis of the data was performed using SPSS 12.0 (SPSS Inc., Chicago, IL, USA) and Excel 2000 (Microsoft Corporation, Redmond, WA, USA). Lin's intra-class correlation coefficient (ICC) was used to assess the intra/inter-examiner reproducibility of the DIAGNOdent Pen.⁴ Poor reproducibility was assessed for ICCs below 0.40, fair reproducibility for ICCs between 0.40 and 0.59, good reproducibility for ICCs between 0.60 and 0.75, and excellent reproducibility for ICCs between 0.75 and 1.00.^{5,6} Analysis by the method of Bland and Altman^{7,8} was used to look for systematic differences and to calculate 95% limits of agreement. Further, for paired readings the mean of the differences between the pairs (DIFF) were determined. The upper and lower limits of agreement, between which 95% of repeated readings were expected to lie, were then represented by $\text{DIFF} \pm 2\text{S.D.}_{\text{DIFF}}$. The range represents the interval between the upper limit of agreement ($\text{DIFF} + 2\text{S.D.}_{\text{DIFF}}$) and the lower one ($\text{DIFF} - 2\text{S.D.}_{\text{DIFF}}$).

According to the treatment related recommendations for using DIAGNOdent cut-off values^{9,10} the reproducibility was tested for following intervals: (1) the whole measurement interval between 0 and 99 with 241 occlusal sites, (2) the interval <30 ($n = 175$) and (3) >30 ($n = 66$). The mean value of all measurements for each site was used to categorise the measurement sites. The ICC and the limits of agreement in each category were calculated.

3. Results

Data of the intra-examiner reproducibility registered for the DIAGNOdent Pen are shown in Table 1. The ICCs revealed an excellent intra-examiner reproducibility; ICCs were found between 0.89 (examiner 4) and 0.92 (examiner 1). Compared with this, large range values were registered for each examiner (41.2–59.1). Only small differences between the first and second measurement were observed for each examiner, which indicate no systematic deviations (see DIFF values in Table 1).

Results for the inter-examiner reproducibility of the DIAGNOdent interval between 0 and 99 can be taken from Table 2. ICCs and the range values were found in the same order of magnitude as mentioned above (ICC: 0.81–0.87; range: 48.3–56.2). While on the one hand high ICCs indicate an

Table 1 – Intra-examiner reproducibility data of the DIAGNOdent Pen

Measurement	Intra-examiner-reproducibility							
	Student 1		Student 2		Dentist 1		Dentist 2	
	1	2	1	2	1	2	1	2
Mean (%)	23.8	25.3	26.7	25.0	21.0	18.4	23.4	24.9
S.D.	24.8	26.3	27.0	25.6	22.8	21.3	26.3	26.8
ICC	0.92		0.88		0.88		0.84	
DIFF	-1.5		1.7		2.6		-1.5	
Range	41.2		51.2		41.4		59.1	

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