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Study Project "Benefits of the DIAGNOcam Procedure for the Detection and Diagnosis of Caries"

Summary of the Final Report

1 The Issue or Question?

The primary question formulated regarding the above-mentioned project addressed the diagnostic accuracy (= validity) of the newly developed DIAGNOcam method (KaVo, Biberach, Germany) compared to clinical and X-ray based examination of proximal surfaces of the permanent dentition.

2 Probands and Methods

In order to answer the question, a prospectively planned in-vivo diagnostic study was conceived and conducted at the Ludwig Maximilian University (LMU) of Munich (Study Director PD Dr. Jan Kuehnisch). The earlier application for ethical approval submitted to the competent ethics commission of the Medical Faculty of the LMU Munich was approved.

Overall, 85 adolescents or adults (47 female / 38 male) with a total of 127 non-cavitated proximal lesions on permanent teeth were examined and validated between the period of April 2012 and February 2013. The course of the study was structured as follows: following the patient screening and the probands' consent to participate in the study, the cleaned and dried interdental spaces were visually examined and the available X-ray images of the bitewings were analysed. As additional evidence, a DIAGNOcam image was taken.

Due to ethical reasons, a validation was only permissible with regard to existing dentine lesions, since enamel lesions are treated preventively and, thus, not invasively. After the identification of existing dentine lesions, a validation of the carious process was performed prior to and after the excavation of the caries. The excavation itself was performed with a self-limiting plastic drill (Polybur, Gebr. Brasseler, Lemgo). The resulting cavity was subsequently moulded and the resulting model was then used for the determination of the depth of the caries. The final filling therapy was performed with the SonicFill system (KaVo, Biberach, Germany and KerrHawe SA, Bioggio, Switzerland).

3 Findings

As a result of the clinical examination, the following main assertions may be made:

1) Comparison between different procedures for the actual extension of the caries

- The visual examination severely underestimated the extension of caries since existing lesions were either missed or it was impossible to correctly predict the actual depth of the caries (Image 1).
- Compared to that, dentine lesions could be correctly diagnosed with a high degree of consistency by using bitewing radiographs. Here, the performed diagnosis correlated with the actual extension of the caries in 122 of 127 cases (96%; Image 1). An underestimation of the caries extension occurred in only five cases.
- In 126 of 127 cases (99%; Images 1; 2; 3) the performed diagnosis through DIAGNOcam images correlated with the actual caries lesion extension. This requires that the lesions have fully penetrated the dental enamel and have reached the enamel-dentine junction extensively. In one case, the extension of the caries was underestimated. This demonstrates a comparably high diagnostic validity of the DIAGNOcam method in comparison to bitewing radiographs.

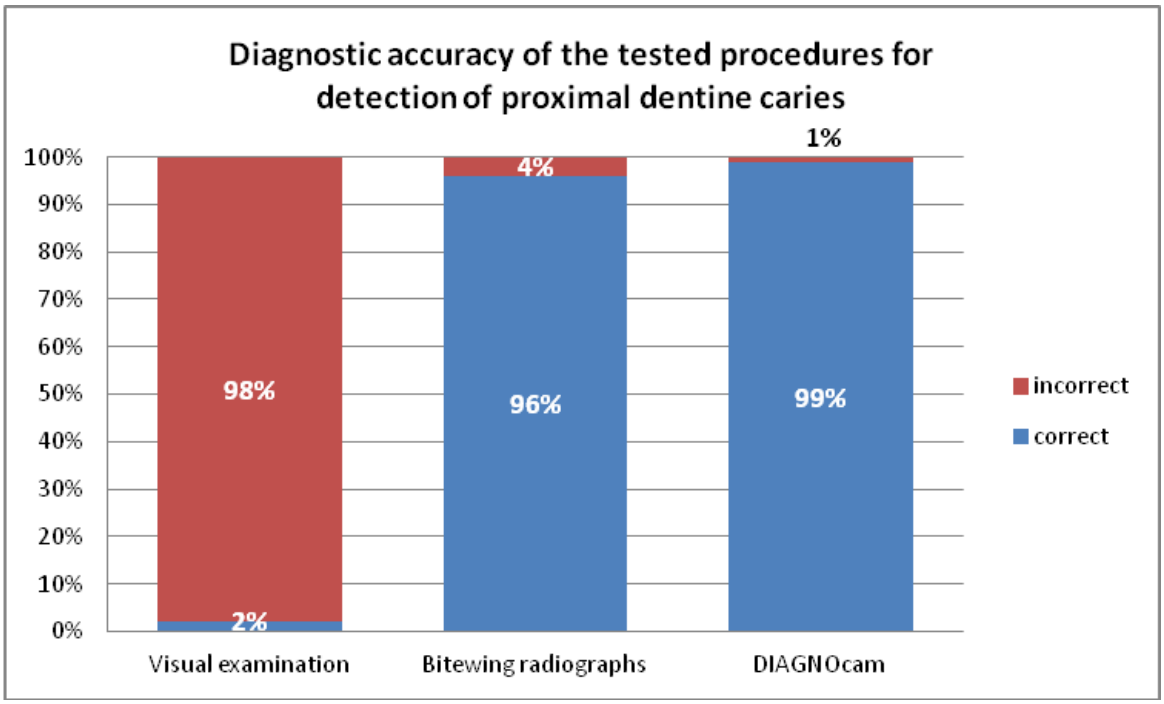

Image 1: Diagnostic accuracy of the tested procedures for detection of proximal dentine caries.

2) Comparison between DIAGNOcam and bitewing radiographs

- The comparison of the diagnostic prediction of dentine caries to the DIAGNOcam and X-ray images correlated very well (96%) if the DIAGNOcam image showed a demineralisation that had fully penetrated the dental enamel and **reached** the enamel-dentine junction (Images 1; 2).

Image 2: The DIAGNOcam image of tooth # 25 shows extensive mesial and distal shadowing, which has already extended to the enamel-dentine junction. The corresponding **bitewing radiograph** indicates a carious process reaching to the outer half of the dentine.

- Advanced dentine lesions can be detected by the less translucent dentine on the DIAGNOcam images, which must be additionally associated with a demineralisation of the dental enamel **including** the enamel-dentine junction. (Image 3). In this context, it should be noted that it was not possible in all cases to show the extension of the lesion in the dentine with the DIAGNOcam. In this case bitewing radiographs may generate additional information.

Image 3: At the distal surface of tooth # 45, the DIAGNOcam image shows lower dentine translucency compared to the dentine not affected by the caries. The carious process has involved the dental enamel and has progressed into the inner half of the dentine. The associated **bitewing X-ray image** points to a carious process also reaching into the inner half of the dentine.

Conclusions and Summary

Based on the present scientific examination data, it can be concluded that the DIAGNOcam procedure can be judged as equivalent in the detection of proximal dentine lesions when compared to the conventional diagnosis with X-rays.
This is remarkable, because DIAGNOcam does not utilize any ionising radiation, thus resulting in clear benefits with regard to radiation hygiene. Moreover, the advantage of an unlimited repeatability – especially with regard to caries monitoring – should not be underestimated.