

Clinical subgingival calculus detection with a smart ultrasonic device: a pilot study

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Abstract

Aim: We have recently tested a surface detection system based on a conventional dental ultrasonic scaler in vitro. The aim of the present study was to investigate sensitivity and the specificity of the detection device in vivo.

Material and Methods: Subgingival buccal surfaces of 63 arbitrarily selected periodontally compromised teeth were scanned intra-orally, while the supragingival positions of the insert, along with the corresponding signals of the detection system, were saved as separate files. After extraction, the surface detection results were evaluated by re-positioning the inserts' position on the tooth in vitro and comparing the detection results with visual findings.

Results: On the scanned tooth surfaces, there were 44 calculus spots, which covered 22.3% of all scanned surfaces (prevalence). The calculus-free surface was divided into "spots" mathematically. The device correctly classified 40 calculus and 125 cementum spots, whereas four calculus and 28 cementum spots were classified incorrectly. Calculus and cementum were discriminated with a sensitivity of 91% and a specificity of 82%. The positive and negative predictive values were 0.59 and 0.97. **Conclusion:** The surface detection device was able to clinically differentiate cementum and calculus in vivo. Therefore, this method may support the decision of whether continued subgingival scaling could damage the cementum.

Grit Meissner¹, Bernd Oehme², Jens Strackeljan³ and Thomas Kocher¹

¹Department of Restorative Dentistry, Periodontology and Pediatric Dentistry, School of Dentistry, Unit of Periodontology, Ernst–Moritz–Arndt University Greifswald, Greifswald, Germany; ²Division of Instruments, Sirona Dental Systems GmbH, Bensheim, Germany; ³Institute of Mechanics, Technical University Magdeburg, Magdeburg, Germany

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The objective of subgingival instrumentation of periodontally diseased root surfaces is to remove the microbial biofilm and the mineralized deposits

Conflict of interest and source of funding statement

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while leaving the cementum intact (Pihlstrom & Ammons 1997, Cobb 2002, Van der Weijden & Timmerman 2002). However, it may often be difficult to differentiate between the existence of calculus and nicks or troughs (Rabbani et al. 1981), and residual deposits are often overlooked when using an explorer (Sherman et al. 1990a, b). Furthermore, the removal of biofilm and calculus may result in roughness and tooth substance loss (Zappa et al. 1991, Kocher et al. 2001a). Therefore, patients may suffer from dentine hypersensitivity after deep scaling (Tammaro et al. 2000) or from a summation of tooth substance loss after many maintenance sessions (Zappa et al. 1991, Ruhling et al. 2004). On

the other hand, residual calculus deposits covered with plaque may prevent complete resolution of the inflamed periodontal pocket (Fujikawa et al. 1988). Only recently, there were reports on several subgingival calculus detection devices, which all lack removal functions (Stambaugh et al. 2002, Krause et al. 2003, 2005, Buchalla et al. 2004). Schwarz et al. (2001, 2003) described an Er: Yag laser-based substrate detection device, which incorporates a feedback-driven treatment mode and thus proved to be an alternative to previous subgingival scaling methods.

Based on laboratory investigations by Strackeljan et al. (1997) Kocher et al. (2000b), we further continued the development of a conventional piezoceramic ultrasound scaler for reliable identification of enamel, cementum and subgingival calculus, which, in the future, should enable the incorporation of feedback-driven power adjustment. At the moment, this device offers the possibility to switch from a detection mode discriminating calculus deposits and clean roots to a treatment mode allowing a conventional ultrasonic treatment with different power levels. We recently demonstrated the system's surface detection capability under laboratory conditions in static tests (Meissner et al. 2005a) as well as under probing movements of the working tip (Meissner et al. 2006a). Furthermore, it could be demonstrated that calculus deposits with a diameter of 0.2 mm could be recogconditions nized under optimal (Meissner et al. 2006b).

This study presents the first results of the in vivo application of this device. A special method was developed allowing an accurate comparison of the detection results taken before and after the tooth extraction (Meissner et al. 2005b). The purpose was to investigate the sensitivity and specificity of calculus detection under clinical conditions.

Material and Methods

Detection device

The detection technique described in this study is based on a conventional piezoceramic ultrasonic scaler as originally described by Strackeljan et al. (1997) Kocher et al. (2000b) and further developed by the authors based on the ultrasonic system Siroson L (Sirona Dental Systems, Bensheim, Germany) with the insert SI 11. The design as well as the function and the analysing algorithm of the detection device have recently been described (Meissner et al. 2005a). In brief, the tip of a conventional ultrasonic scaler receives weak impulses with a frequency of about 50 Hz, which makes the instrument's tip oscillate with a diameter of $5 \,\mu m$ at the scanned surface. The surface itself is thereby stimulated to oscillate, the frequency being dependent on the substrate characteristics, namely cementum or calculus. These oscillations are transferred back into the instrument for subsequent analysis by a computerized system.

Samples

After approval by the local ethics committee, 26 patients from private dental Table 1. Demographic data of enrolled teeth: number of all evaluated teeth

	Female		Male		Total
	maxillary	mandibular	maxillary	mandibular	
Anterior	3 (3)	22 (8)	13 (1)	18 (6)	56 (18)
Premolar	2 (0)	2 (0)	1 (1)	1 (0)	6 (1)
Molar	0	0	1 (0)	0	1

Subset of treated teeth in parentheses.

practices were enrolled in the study. After obtaining informed consent, 78 teeth (68 anterior, seven pre-molar and three molars) that were to be extracted because of advanced periodontal disease (Table 1) were included in the study. The main inclusion criteria were probing depths of 6 mm or more on teeth and that the supragingival portion of included teeth could be visualized intra-orally using our custom-made camera set-up, which limited the test to buccal and buccal approximal surfaces and rather anterior teeth. Whether or not the teeth had been treated for periodontal disease previously did not influence inclusion. Similarly, mobility had no influence on study enrollment because each tooth was splinted in a mount. The actual presence of calculus on the selected teeth was unknown to the examiner at the beginning of the study because we also intended to detect calculus-free areas to test whether the device was able to identify cementum correctly.

Experimental set-up

During subgingival movements with any detection device in vivo, the subgingival root surface is covered with gingiva, and it is therefore impossible to validate the detection results directly. For the validation of intra-oral (in vivo) results, we developed a method that actually compared subgingival root surface detection results with the objective (in vitro) findings after tooth extraction (Meissner et al. 2005b). In brief, intraoral scanning movements with the supragingival ("visible") part of the ultrasonic insert and an attached threedimensionally (3D) folded wire attached to the tip base ("3D needle") were recorded with a small camera (ToUcam, Philips, Hamburg, Germany). This camera was attached to a modified intra-oral X-ray film mount (Kentzler-Kaschner Dental, Ellwangen, Germany). The clenched part of the X-ray mount was covered with putty impression material (Panasil, Kettenbach-Dental; Eschenburg, Germany) to affix the tooth in a reproducible position, which allows for the subsequent re-location of the insert's exact position on the then extracted tooth in vitro. This impression, which included the tooth and its next agonists and antagonists, held the camera in place during subgingival intra-oral scanning. Therefore, only the described surfaces could be investigated during the study (Fig. 1a and b).

Protocol

In order to re-position the insert accurately, a waterproof pen was used to mark the supragingival crown with three vertical and one horizontal reference lines (Meissner et al. 2005b). The horizontal reference line along the buccal gingival margin defined the coronal pocket border after the extraction. The examiner, wearing magnifying eyeglasses (\times 2.5 magnification; Carl Zeiss, Jena, Germany), systematically moved the detection tip over the mesiobuccal, midbuccal and distobuccal surface (limited by the extra-orally positioned camera) in a slow scanning motion in a corono-apical direction. The manual motion amplitude was about 1 mm on the root surfaces. As suggested when working with an ultrasonic scaler, the examiner aimed to position the instrument's tip in a rather small angle to the tooth surface (Flemmig et al. 1998).

Captured video images of the tooth and the supragingival positions both of the ultrasonic tip and the "3D needle", along with the corresponding computergenerated signals of the detection system, were saved as separate video and data files in a synchronized way. After extraction, the tooth and the camera were re-positioned into the mount in order to capture live images in exactly the same position of the camera in relation to the tooth (Fig. 1c and d). The data files were then screened for sequences, in which the detection system detected calculus. The video images corresponding to these calculus signals,



Fig. 1. Experimental set-up. (a) In vivo: To record the supragingival tip movements along with the corresponding results of the detection system during the subgingival scan in the patients' mouth, a video camera is attached onto an X-ray mount, which is fixed intra-orally with putty impression material. (b) Extra-oral experimental set-up: the scanned teeth were extracted and adhesively fixed in their position in the impression material, thus exactly mirroring their intra-oral position. (c) Example of the intra-oral position of the insert during the surface scan in vivo: a video sequence of the in vivo scan corresponds to the extracted data sequence (calculus detection). (d) Example of the in vitro re-positioning of the tip: the extra-oral situation with the entire root exposed matches exactly the intra-oral position of the instrument in (c).

which contained information on the exact insert positions, were extracted from the video file as a picture. The insert was then re-positioned on the extracted tooth until the live image showed the same position of the insert on the tooth as on the captured intra-oral video image (Fig. 1c and d). Whether or not the tip of the insert was positioned on calculus was verified with magnifying glasses ($\times 2.5$, Carl Zeiss).

For the determination of the prevalence of calculus, all calculus areas of the scanned subgingival root surfaces were photographed with an incidental light microscope using a $\times 20$ magnification (Olympus Optical Co., Hamburg, Germany) connected to a video camera (Sony Power HAD, Model 950 P, Tokyo, Japan). The areas with cementum and calculus were measured with an image analysis program (analySIS 3.0, Soft Imaging System, Münster, Germany).

Raw data processing and evaluation

The video stream recorded 15 frames per second. The speed of the tip during regular scanning movements on the root surface was about 6 mm/s (0.4 mm between two pictures, which are 66 ms apart). Because the software of the surface detection system recorded data only every 300 ms, the tip could have moved 1.8 mm between individual measuring points, which justifies a distance of 0.9 mm between the tip position and the closest calculus spot to be taken as a correct identification. Likewise, only calculus spots with a diameter of at least 1 mm were included. The accuracy of in vitro re-positioning of the insert on the extracted tooth has been practiced and was found to be reproducible with a variability of 1 mm. Therefore, in case of in vitro verified calculus within a circle of 1 mm diameter of the extra-orally repositioned tip on the root surface, the measurement was classified as correct.

All positive (calculus) detection signals (both true and false positive) were evaluated. Then, all scanned root surfaces were examined for calculus spots that had not been found by the detection system (false negative). Calculus spots found on subgingival tooth surfaces, which were unintentionally not scanned by the examiner, were omitted from further analysis, because this was the fault of the examiner rather than the device (proof in videomaterial).

The remaining cementum surface was correctly identified as such (correct negative), although it was impossible to realign all positions of the insert on



number of all cementum = (prevalence cementum {77,7 %}) x (number of calculus spots {44}) spots prevalence of calculus {22,3 %}

Fig. 2. Mathematical determination of all scanned insert positions on the cementum. (a) Clinically assessed and microscopically delineated root surface area with circumscribed calculus {C}. The cementum surface area is the difference between the delineated root surface and the circumscribed calculus areas. (b) The recorded in vivo path of the detection insert over the root surface. (c) The unknown number of all cementum spots (blue circle) were computed by division of prevalence of microscopically determined cementum multiplied by the number of microscopically enumerated calculus spots (yellow circles) divided by the calculus prevalence. On all teeth together, we found 44 calculus spots. The diameter (1 mm) of the spot was a consequence of the measurement technique and accuracy.

the cementum with the chosen experimental set-up. In order to calculate the sensitivity and specificity, the number of correctly detected cementum spots was therefore determined mathematically in parallel to the available calculus data. The percentage of cementum and calculus areas was determined, and the total number of calculus spots on the tested teeth (both detected and not detected) was correlated to the calculus area. The amount of correctly identified cementum spots (correct negative) was then computed by applying this ratio to the measured cementum surface (see the formula in Fig. 2).

Data analysis

Using the numbers determined as described above, the predictive values, sensitivity and specificity of the detection device were calculated. However, because the optimal conditions for surface detection using this device have been studied in vitro previously

(Meissner et al. 2005a, 2006a, b), and the video material allowed to distinguish these from inherently less favourable conditions for surface detection, we made an attempt to analyse the detection results separately under "optimal" conditions in addition to the primary aim, which just addressed the characteristics of the device under "realistic" clinical conditions, regardless of the factors interfering with the detection process. In a subsequent subgroup analysis, which was derived from the data pool by eliminating sequences with proof for artefacts caused by touching crown margins, by additional contacts of enamel or an adjacent tooth with the proximal part of the tip, touching the surface with the front or back side of the insert instead of the lateral side, or by jamming movements, the same results were found as for the results at large (Table 2).

The sensitivity, specificity, positive and negative predictive values (ppV, npV) for "realistic" and "optimal" *Table 2.* Detection results of the in vivo detection, verified in vitro after tooth extraction in all positions where the detection system indicated calculus

	Number of identified spots with			
	calculus	cementum	sum	
Test result				
Positive	40	28 (12)	68 (52)	
Negative	4	125	129	
Total	44	153 (137)	197 (181)	

Numbers in parentheses indicate the same results with the exclusion of potential artifacts (such as touching crown margins, double contact of the tip at an adjacent tooth, touching the surface with the front or back side of the insert, or jamming movements).

conditions were determined, calculated and discussed separately.

Results

Out of the 78 teeth from 26 patients, the information of 15 teeth (6 patients) was lost during data processing and transfer. Thus, only the data of 63 teeth from 20 patients (56 anterior, six pre-molar, one molar) could be assessed. On these teeth, we objectively verified 54 individual calculus spots extra-orally, out of which 10 had unintentionally not been scanned and were therefore omitted from further analysis. Out of the remaining 44 calculus spots, 40 were correctly identified (correct positive), whereas four calculus spots were not detected (false negative). Out of 68 positive results, 28 did not correspond to actual calculus spots (false positive). Because a total of 153 spots were mathematically attributed to the cementum surface area, the number of correctly identified calculus-free spots (correct negative) was 125 (see Fig. 2, Table 2). The scanned root surface area consisted of 77.7% cementum and 22.3% calculus (prevalence). Thus, including the complete set of data ("realistic" conditions), calculus and cementum were discriminated with a sensitivity of 91% and a specificity of 82%. The positive predictive value (ppV) was 0.59, and the negative predictive value (npV) was 0.97.

Exclusion of visually proven artefacts during the instrumentation (16 falsepositive detection results, "optimal" conditions, Table 2) resulted in a sensitivity of 91% and a specificity of 91% (ppV: 0.76; npV: 0.97).

Discussion

The present study describes the results from the first clinical application of an ultrasound-based automated subgingival root surface detection system. Compared with our former in vitro results for calculus detection using a predecessor of the tested device (sensitivity 76%, specificity 86%) (Meissner et al. 2006a), the present study, which was now performed under influences of the oral cavity (body temperature, contact to gingiva, saliva and blood) and clinical handling variables (contact pressure and working angles), did not yield a decreased ability of the detection device to recognize cementum and calculus.

Compared with the standard procedure based on the tactile probing with an explorer (sensitivity 23%, specificity 88%) (Sherman et al. 1990b), the new detection system is superior (sensitivity 91%, specificity 82%). The ppV of 0.59 demonstrates how many of the present calculus spots can actually be detected. In contrast, the npV of 0.97 shows how many of the detected cementum areas are really there. These values depend on the prevalence of the calculus found. If the prevalence of calculus would be twice as much (44%), the ppV increases to 0.80, but the npV declines to 0.91. This corresponds to a higher chance to detect calculus if there is more calculus on the root surfaces. If, at an identical sensitivity and specificity of the test device, the prevalence would be 11%, the ppV would decline to 0.39 while the npV would increase to 0.98. Hence, the detection device may reduce the risk to overtreat cementum with adhering biofilm and without calculus, because the power setting should only be high if the insert encounters calculus and low if there is only biofilm. However, the prevalence of calculus found on the examined teeth corresponded to the results of other studies, where approximal root surfaces of periodontally involved teeth showed a calculus prevalence of 30% (Gurgan & Bilgin 2005) and 22% (Kocher et al. 2000a).

The limitation to buccal and buccal approximal surfaces was not due to the device, but rather the necessity to record simultaneously the precise location of the insert in every scanning position. We found the extra-orally positioned camera the only way to do this, which limited the test to these surfaces and to anterior teeth. Although the results of this in vivo study confirm that the device functions under clinical conditions, the question remains whether these will also be applicable in regions not studied in this investigation (like distal and lingual areas, multirooted teeth and furcations).

It has to be considered that the potential of the detection method also depends on the scanning skills of the dentist. As our results show, 10 existing calculus spots were not recognized because the area was just not scanned. Furthermore, there may be false-positive results, which cannot be distinguished from artefacts due to unintentional contacts of the tip. Because these detections would have led to overtreatment in the clinical situation, they were all counted towards the results. However, because they do not represent the detection capabilities of the device per se, a subgroup analysis excluding visually proved artefacts has been included in this report. Because only false-positive results dropped out during the subgroup analysis, this resulted in an increased specificity (91% rather than 82%), while the sensitivity remained the same (91%) (see Table 2). Many in vivo studies of new devices for periodontal therapy have claimed to investigate the potential of these devices, but they also relied on the judgement of the dentist, who scanned and subsequently treated the root surfaces until he considered it to be clean. After extraction, the residual deposits were assessed (Yukna et al. 1997, Huerzeler et al. 1998, Kocher et al. 2002, Geisinger et al. 2007). Thus, in addition to the equipment used, the skills and experience of the dentist markedly influenced the final outcome, if this approach is followed. Moreover, it is impossible to say whether the cementum has actually been removed without subsequent histology (Ruhling et al. 2004). In contrast to the studies cited above, the authors of this study tried to dissect the operator's and the device's capability. However, we had to accept an inaccuracy of about 1 mm in order to obtain a close reproduction of intra-oral subgingival conditions. Furthermore, we did not treat any surface. because this would have blurred the detection results of the device. Thus, our study emphasizes the capability of the device itself as much as possible.

The detection device described in this paper is a part of a feedback-driven detection and treatment instrument. The only comparable system that currently combines calculus identification and feedback-driven removal is the Keylaser III (Kavo, Biberach, Germany). It augments an Er:Yag laser

with a diode laser (DIAGNOdent, KaVo) as a detection device. A feedback-driven treatment mode is enabled and the system is an alternative to previous subgingival scaling methods (Schwarz et al. 2001, 2003). In addition, the recently introduced endoscopy-based device Dental View[®] (Dental View, Irvine, CA, USA) (Stambaugh et al. 2002, Geisinger et al. 2007) and the optical system DetekTar (Ultradent Products, South Jordan, UT, USA) (Krause et al. 2005) improve surface recognition compared with classical systems, but still rely on an additional instrument for treatment. While changing instruments, it may happen that originally detected spots are not reproducibly found again, which may then lead to overtreatment of the surrounding cementum.

There is an ongoing debate on whether calculus contributes to the progression of periodontal disease. Former studies already found that tiny polished calculus spots show a similar tendency to heal as a cleaned, calculus-free root surface (Nyman et al. 1988, Kocher et al. 2001b). Histology showed that these spots are well tolerated (Nyman et al. 1988), which has not been demonstrated for larger deposits. It was demonstrated that periodontal destruction is associated with the existence of calculus (White 1997, Tan et al. 2004). Clinical and microscopic tests proved that the reaction on calculus and plaque was more severe than on plaque alone (Schwartz et al. 1971). The dental calculus was described as a porous substrate, which can adsorb a variety of toxic products and retain significant levels of endotoxin, which itself damages tissue (White 1997). The subgingival calculus surfaces are always covered with a layer of unmineralized, viable and metabolically active bacteria, and a minimum of subgingival calculus may extend the radius of damage associated with plaque (Mandel & Gaffar 1986, White 1997, Tan et al. 2004). This is the reason why dentists still insist on thoroughly cleaned, calculus-free root surfaces as an endpoint of a treatment (Pihlstrom & Ammons 1997, Cobb 2002).

In summary, the ability of the calculus detection method presented in this study may ease periodontal treatment, which aims to remove subgingival calculus, while preserving cementum. Even though the study method did not enable intra-oral visualization of surface detection, it reproduced the intra-oral situation after extraction and allowed to evaluate the surface detection capabilities of the tested device. The sensitivity and specificity found in this study are comparable to our former in vitro findings. A combination of treatment and detection modes in one instrument may help to remove an identified calculus deposit precisely without changing the instrument. The best way to prove the benefit of a device like this would be a clinical study. Thereby, clinically relevant parameters like change of pocket depth, attachment level and occurrence of hypersensitivity after subgingival scaling could show a potential benefit of the new device compared with conventional or alternative treatment.

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Address:

Grit Meissner Zentrum für Zahn-, Mund- und Kieferheilkunde Abt. Parodontologie Rotgerberstr. 8 D-17487 Greifswald Germany E-mail: grit.meissner@uni-greifswald.de

Clinical Relevance

Scientific rationale for the study: A major goal of periodontal therapy is to remove subgingival calculus, while the cementum should be preserved. Here, we present the first in vivo study of an automated calculus detection device based on a

modified piezoceramic ultrasonic scaler.

Principal findings: It could be shown that the tested device discriminates subgingival calculus and cementum under clinical conditions in vivo. *Practical implications*: If incorporated into a combined detection/ treatment system, the device tested in this study may help dentists and auxiliary personnel to discriminate subgingival calculus from the cementum in order to remove calculus selectively during subgingival ultrasonic scaling. This document is a scanned copy of a printed document. No warranty is given about the accuracy of the copy. Users should refer to the original published version of the material.