IN VITRO EVALUATION OF A DIFFERENTIAL REFLECTOMETRY DENTAL CALCULUS DETECTION INSTRUMENT.

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ABSTRACT

Objectives: The presence of subgingival dental calculus on tooth root surfaces, an important risk factor in the pathogenesis of human periodontitis, is clinically challenging to reliably detect with existing tactile-based, manual forms of dental instrumentation.

In 2003, the United States Food and Drug Administration granted approval for marketing in the United States of a differential reflectometry-based device (DetecTar, NEKS Technologies, Laval, Quebec, Canada) for detection of subgingival dental calculus in humans. The instrument employs a light-emitting diode to deliver red light from the visible light region of the electromagnetic spectrum, with a 635 nm-specific wavelength, onto tooth root surfaces through an optical fiber extending to the tip of a periodontal probe-like handpiece. The optical fiber also collects light reflected back from oral surfaces, from which the optical signature of dental calculus is identified by matching the spectra of the reflected light to an internal computer software database containing red light spectra characteristic of dental calculus in its reference library. To date, only a limited amount of in vitro and in vivo research has been conducted on the DetecTar differential reflectometry device.

As a result, the purpose of this study was to to assess, with an in vitro typodont model system, the ability of the DetecTar differential reflectometry device to reliably identify subgingival dental calculus on tooth root surfaces.

Methods: A total of 108 subgingival sites on mandibular posterior plastic teeth, of which 73 (67.6%) exhibited artificial dental calculus deposits, were mounted within typodont models of the human oral cavity, comprised of white plastic teeth emerging from and surrounded by anatomically-accurate pink silicone gingival and palatal soft

tissues. Each typodont was attached to a phantom head with simulated soft tissue mouth shrouds. Sheep blood was irrigated into subgingival and interproximal areas around typodont teeth to simulate gingival tissue inflammation, and artificial saliva applied onto supragingival typodont tooth surfaces to further simulate typical oral cavity conditions in humans. The 108 test subgingival surfaces were then evaluated with the DetecTar differential reflectometry device in duplicate readings performed by a single periodontist examiner blinded to the typodont distribution of subgingival dental calculus. Emission of a sustained audible signal tone from the DetecTar differential reflectometry device upon entry of its optical fiber tip into typodont periodontal pockets indicated detection of subgingival dental calculus. The diagnostic performance of the DetecTar differential reflectometry device, relative to in vitro detection of subgingival dental calculus, was assessed among all test root surfaces, as well as among proximal and non-proximal root surfaces, with calculations of sensitivity, specificity, positive predictive value, negative predictive value, positive likelihood value, negative likelihood value, diagnostic odds ratio, accuracy (diagnostic effectiveness), and Youden's Index.

Results: Among all root surfaces, the DetecTar differential reflectometry device revealed a sensitivity of 75.4%, specificity of 86.3%, positive predictive value of 86.0%, negative predictive value of 75.9%, positive likelihood value of 5.5, negative likelihood value of 0.3, diagnostic odds ratio of 19.6, accuracy (diagnostic effectiveness) of 80.6%, and Youden's index value of 0.62, for in vitro detection of subgingival dental calculus. More favorable diagnostic test findings for the device were found on non-proximal (buccal and lingual) than proximal (mesial and distal) root surfaces, with accuracy (diagnostic effectiveness) values 22.7% lower at proximal sites, indicating a poorer

performance capability of differential reflectometry within interproximal periodontal pockets. Only a fair level (kappa = 0.42) of reproducibility was found in duplicate scoring of tooth root surfaces for subgingival dental calculus by the DetecTar differential reflectometry device.

Conclusions: These study findings suggest marked limitations in the potential clinical utility of the DetecTar differential reflectometry device for detection of subgingival dental calculus. The device demonstrated markedly decreased in vitro accuracy on mesial and distal typodont tooth root surfaces, as compared to non-proximal tooth sites, and exhibited only a fair level of reproducibility in duplicate assessments. The overall performance of the DetecTar differential reflectometry device appears to be inferior to similar assessments of typodont tooth root surfaces conducted by other investigators with more conventional tactile-based, manual instrumentation. Based on these in vitro findings, routine clinical utilization of the DetecTar differential reflectometry device in dental practice is not recommended.

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CHAPTER 1

INTRODUCTION

The presence of subgingival dental calculus on tooth root surfaces is an important risk factor in the pathogenesis of human periodontitis (Mandel & Gaffar 1986). In a 15-year longitudinal study in Sri Lanka of tea laborers left without professional dental care or home plaque control training, teeth with subgingival dental calculus experienced a significantly greater rate of clinical periodontal attachment loss as compared to those devoid of detectable subgingival dental calculus (Anerud et al. 1991). Subgingival dental calculus deposits have also been significantly associated with the occurrence over six years of progressive clinical periodontal attachment loss in adults diagnosed with early-onset forms of periodontitis (Albandar et al. 1998).

Subgingival dental calculus is clinically challenging to reliably detect with existing tactile-based, manual forms of dental instrumentation. Dental explorers and periodontal probes of various shapes and configurations have been used to feels for surface irregularities on tooth roots as a surrogate assay in lieu of direct visual inspection of subgingival sites afforded by periodontal flap surgery. High false negative diagnostic findings have been reported with conventional manual explorer detection of subgingival dental calculus, with 77.4% of tooth root surfaces remaining positive for subgingival dental calculus after periodontal root instrumentation being wrongly judged as dental calculus-negative by dental explorers (Sherman et al. 1990). Another study where two clinical examiners scored the same periodontal sites for subgingival dental calculus after the completion of periodontal root instrumentation found poor agreement between their assessments. In that study, less than one-half of the time was joint agreement recorded on subgingival dental calculus detection for subgingival dental calculus-positive sites (Pippin & Feil 1992).

In 2003, the United States Food and Drug Administration granted approval for marketing in the United States of a differential reflectometry-based device (DetecTar, NEKS Technologies, Laval, Quebec, Canada) for detection of subgingival dental calculus in humans. The instrument employs a light-emitting diode to deliver red light radiation from the visible light region of the electromagnetic spectrum, with a 635 nm-specific wavelength, onto tooth root surfaces through an optical fiber extending to the tip of a periodontal probe-like handpiece. The optical fiber also collects light reflected back from oral surfaces, from which the optical signature of dental calculus is identified by matching the spectra of the reflected light to an internal computer software database containing red light spectra characteristic of dental calculus in its reference library. To date, only a limited amount of in vitro and in vivo research has been conducted on the DetecTar differential reflectometry device, which is discussed as follows.

Krause et al. (2003) examined 20 extracted teeth with root surface dental calculus, and found 100% correct identification of dental calculus-positive and dental calculus-negative tooth root surfaces with the DetecTar differential reflectometry device. In this study deposits as small as 0.1 mm in size were successfully detected by the device. The presence of blood slightly reduced the sensitivity of device, particularly when it was used at lower angulation values between the device probe tip and the evaluated tooth surface (Krause et al. 2003).

Kasaj et al. (2008) examined 96 subgingival human root surfaces on teeth scheduled for extraction, and on 80 DetecTar-positive root surfaces, carried out periodontal scaling and root planing until the tooth surfaces became DetecTar-negative upon repeated assessment. A total of 89% of DetecTar-positive tooth root surfaces had calculus present, and 90% of DetecTar-negative root surfaces were calculus-free, in microscopic examinations conducted after tooth extraction. After the completion of periodontal scaling and root planing and tooth extraction, 83% of DetecTar-negative surfaces after periodontal scaling and root planing were found to be calculus-free in post-extraction microscopic examinations (Kasaj et al. 2008).

Shakibaie & Walsh (2012) mounted 30 extracted human teeth with dental calculus into three manikin heads with silicone gingiva, and scored for subgingival calculus in the artificial periodontal pockets with the DetecTar differential reflectometry device and a Williams periodontal probe. The DetecTar differential reflectometry device had a higher level of accuracy (79% vs. 60%) and better reproducibility (mean Kappa = 0.54 vs. 0.39) for detection of subgingival dental calculus than a Williams periodontal probe (Shakibaie & Walsh 2012).

As a result of the limited research data to date on the DetecTar differential reflectometry device, the purpose of this study was to further assess, using an in vitro typodont model system, the ability of the DetecTar differential reflectometry device to reliably identify subgingival dental calculus on tooth root surfaces.

CHAPTER 2

MATERIALS AND METHODS

Laboratory Facilities

All study procedures were performed using non-human and non-animal materials in the Graduate Periodontology Clinic located in the Temple University Maurice H. Kornberg School of Dentistry on the Temple University Health Sciences Center campus in Philadelphia, Pennsylvania. Since the data for the present non-clinical, laboratory-based, study was obtained without any intervention or interaction with living individuals, and did not involve any identifiable private information, the research activity did not involve human subjects, as defined by United States Department of Health and Human Services regulations at 45 CFR part 46.116(f), and did not require a human subjects institutional review board approval, per a written determination issued by the Temple University Human Subjects Protections Institutional Review Board.

Test Tooth Root Surfaces

A total of 108 subgingival sites on mandibular posterior plastic teeth (Kilgore International, Inc., Coldwater, MI), of which 73 (67.6%) exhibited artificial dental calculus deposits, were mounted within a total of three typodont models of the human oral cavity, comprised of white plastic teeth emerging from and surrounded by anatomically-accurate pink silicone gingival and palatal soft tissues (Kilgore International, Inc., Coldwater, MI) (Figure 1).

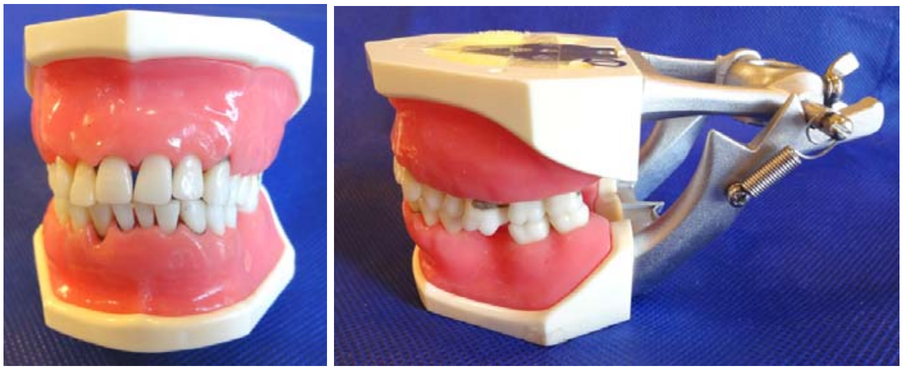

Figure 1. Front view (left), and lateral view (right) of typodont model.

Mandibular posterior teeth (N = 9 premolar and molar teeth) were used to remove examiner access and visualization as an issue (Figure 2).

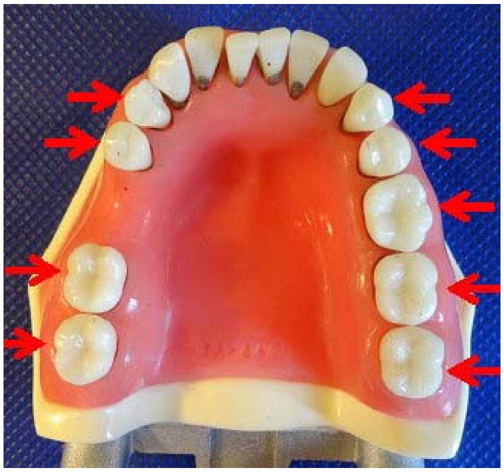

Figure 2. Mandibular portion of typodont model with arrows indicating location of test teeth for subgingival dental calculus detection.

Plastic teeth with and without dental calculus deposits were randomly distributed throughout the posterior mandibular portions of the three typodont models (Figure 3).

Figure 3. Examples of dental calculus-free (left) and artificial dental calculus-positive plastic teeth mounted in posterior mandible of typodont models.

Plastic teeth with artificial dental calculus present on root surfaces were positioned in the typodont models so that the dental calculus was located in a subgingival area beneath the coronal edge of the pink silicone gingival soft tissues (Figure 4).

Figure 4. Example of subgingival location on typodont model of artificial dental calculus-positive molar tooth surface.

Each typodont was attached to a phantom head with simulated soft tissue mouth shrouds (Figure 5).

Figure 5. Phantom head with mounted typodont model of oral cavity.

Defibrinated sheep blood was irrigated into subgingival and interproximal areas around typodont teeth to simulate gingival tissue inflammation, and artificial saliva applied onto supragingival typodont tooth surfaces to further simulate typical oral cavity conditions in humans (Figure 6).

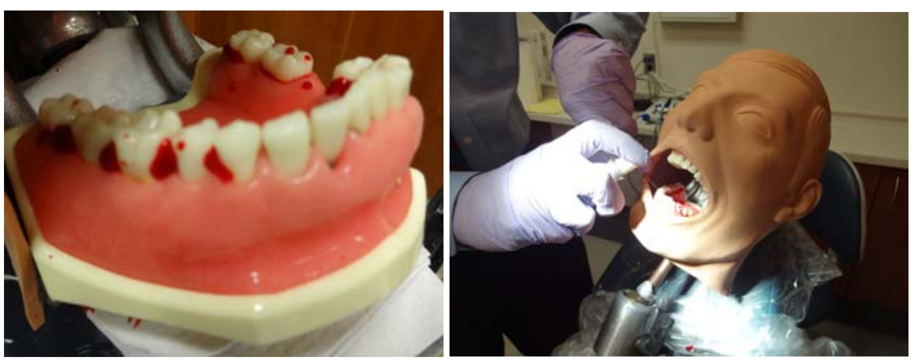

Figure 6. Sheep blood irrigated into subgingival and interproximal typodont areas (left), and artificial saliva applied (right) to supragingival tooth surfaces to simulate normal oral cavity environment where inflammatory periodontitis is present.

Assessments with DetecTar Differential Reflectometry Device

The 108 test subgingival surfaces were evaluated with a DetecTar differential reflectometry device (NEKS Technologies, Laval, Quebec, Canada) (Figure 7), which was calibrated following instructions of the manufacturer prior to each use.

Figure 7. DetecTar device with internal computer housed in unit base (left), with an optical probe embedded within a periodontal probe-like handpiece (upper right), and activated via a foot-depressed switch (lower right).

Emission of a sustained audible signal tone from the DetecTar differential reflectometry device upon entry of its optical fiber tip into typodont periodontal pockets indicated detection of subgingival dental calculus (Figure 8).

Figure 8. Example of DetecTar periodontal probe-like tip (left) being placed into a subgingival site on typodont model (right).

Duplicate DetecTar readings of test root surfaces were performed by a single periodontist examiner (Dr. Jennifer A. Lopes), who was kept blind and unaware as to the distribution of subgingival dental calculus on test teeth in the three typodont models (Figure 9).

Figure 9. Periodontist examiner employing DetecTar device on mounted typodont model.

Data Analysis

Using 2x2 contingency table analysis, sensitivity, specificity, positive predictive value, negative predictive value, positive likelihood value, negative likelihood value, diagnostic odds ratio, accuracy (diagnostic effectiveness), and Youden's Index, were calculated to assess the diagnostic performance of the DetecTar device relative to in vitro detection of subgingival dental calculus (Shaikh 2011).

As detailed by Shaikh (2011), sensitivity was defined as the probability that the DetecTar device will be positive when root surface calculus is detected (true positive rate). Specificity was defined as the probability that the DetecTar device will be negative when root surface dental calculus is not detected (true negative rate). Positive predictive value was defined as the probability that root surface calculus is detected when the DetecTar device is positive. Negative predictive value was defined as the probability that root surface calculus is not detected when the DetecTar device is negative. Positive likelihood value shows how much the odds that root surface calculus is detected is increased when the DetecTar device is positive. Negative predictive value shows how much the odds that root surface calculus is detected is decreased when the DetecTar device is negative. Diagnostic odds ratio was used as an overall measure to summarize the discriminative ability of the DetecTar device in detecting dental calculus-positive vs. calculus-negative root surfaces. Accuracy (diagnostic effectiveness) was the proportion of tooth root surfaces correctly categorized by the DetecTar device. Youden’s index was also used as a global measure of overall discriminative power of the DetecTar device to summarize its sensitivity and specificity (Shaikh 2011).

Kappa analysis (Hunt 1986) was performed to quantify agreement beyond chance for the reproducibility of duplicate scoring of root surfaces for subgingival dental calculus by the DetecTar device. Kappa values between 0.40 and 0.75 were considered to represent fair to good agreement, with those > 0.75 indicating excellent agreement (Hunt 1986).

The PC-based STATA/SE 14.2 for Windows (StataCorp PL, College Station, TX USA) 64-bit statistical software package was used in the data analysis.

CHAPTER 3

RESULTS

Test Tooth Root Surfaces

The results of DetecTar device analysis of all 108 test root surfaces for in vitro detection of subgingival calculus is presented in Table 1.

Table 1. Distribution of all tooth root surfaces by DetecTar device response and presence or absence of dental calculus

		Root surface dental calculus present	Root surface dental calculus absent
DetecTar device response	positive	43	7
	negative	14	44

Using 2x2 contingency table analysis, the DetecTar device responses, relative to the presence or absence in vitro of subgingival dental calculus for all tooth surfaces, show a sensitivity (true positive rate) = 75.4%, a specificity (true negative rate) = 86.3%, a positive predictive value = 86.0%, a negative predictive value = 75.9%, a likelihood ratio for positive test = 5.5, a likelihood ratio for negative test = 0.3, a diagnostic odds ratio = 19.6, a diagnostic effectiveness (accuracy) = 80.6%, and a Younden’s index = 0.62.

The distribution of DetecTar device responses scored between duplicate examinations of 108 tooth root surfaces is presented in Table 2.

Table 2. Distribution of DetecTar device responses between duplicate examination of 108 tooth root surfaces

		DetecTar device response at examination #2	
		positive	negative
DetecTar device response at examination #1	positive	43	7
	negative	14	44

Only a fair level (kappa = 0.42) of reproducibility was found in duplicate scoring of tooth root surfaces for subgingival dental calculus by the DetecTar differential reflectometry device.

Using data from both examinations, the results of DetecTar device analysis of proximal (mesial and distal) test root surfaces for in vitro detection of subgingival calculus is presented in Table 3.

Table 3. Distribution of proximal tooth root surfaces scored in both examinations #1 and #2 by DetecTar device response and presence or absence of dental calculus

		Root surface dental calculus present	Root surface dental calculus absent
DetecTar device response	positive	47	7
	negative	26	28

Using 2x2 contingency table analysis, the DetecTar device responses, relative to the presence or absence in vitro of subgingival dental calculus for proximal tooth surfaces, show a sensitivity (true positive rate) = 64.4%, a specificity (true negative rate) = 80.0%, a positive predictive value = 87.0%, a negative predictive value = 51.9%, a likelihood ratio for positive test = 3.2, a likelihood ratio for negative test = 0.5, a diagnostic odds ratio = 7.2, a diagnostic effectiveness (accuracy) = 69.4%, and a Younden’s index = 0.44.

In comparison, and also using data from both examinations, the results of DetecTar device analysis of non-proximal (buccal and lingual) test root surfaces for in vitro detection of subgingival calculus is presented in Table 4.

Table 4. Distribution of non-proximal tooth root surfaces scored in both examinations #1 and #2 by DetecTar device response and presence or absence of dental calculus

		Root surface dental calculus present	Root surface dental calculus absent
DetecTar device response	positive	37	7
	negative	4	60

Using 2x2 contingency table analysis, the DetecTar device responses, relative to the presence or absence in vitro of subgingival dental calculus for non-proximal tooth surfaces, show a sensitivity (true positive rate) = 90.2%, a specificity (true negative rate) = 89.6%, a positive predictive value = 84.1%, a negative predictive value = 93.8%, a likelihood ratio for positive test = 8.6, a likelihood ratio for negative test = 0.1, a diagnostic odds ratio = 78.6, a diagnostic effectiveness (accuracy) = 89.8%, and a Younden's index = 0.80. It is noteworthy that more favorable diagnostic test findings for the DetecTar device were found on non-proximal (buccal and lingual) than proximal (mesial and distal) root surfaces, with accuracy (diagnostic effectiveness) values 22.7% lower at proximal sites (89.8% vs. 69.4%).

CHAPTER 4

DISCUSSION

Several important findings may be drawn from this study. First, the DetecTar differential reflectometry device exhibited only a fair level of reproducibility in duplicate assessments of tooth root surfaces for subgingival dental calculus. This is of great concern, since the marked variability in device outcomes under ideal in vitro examination conditions, raises questions about the ability of the DetecTar device to provide consistent assessments over time. If the instrument readings are subject to inherent variability in assessing identical tooth root surfaces, then it is difficult to draw firm diagnostic conclusions about whether or not subgingival dental calculus is actually present at a given site. This then presents a significant dilemma for clinicians who are attempting to make therapeutic decisions based on DetecTar device findings – is the device accurate in evaluating non-visible root surfaces submerged in periodontal pockets? Until better DetecTar device reproducibility data becomes available, its reliability remains in doubt.

Previous studies of the DetecTar differential reflectometry device give little insight into the device reproducibility question raised by this study. In comparison to the kappa intra-examiner value of 0.42 found in this study, a single other study by Shakibaie & Walsh (2012) reported an kappa intra-examiner score of 0.54, which is still in the fair to good range.

A second concern about the DetecTar differential reflectometry device is the relatively poor diagnostic performance the instrument displayed at proximal (mesial and distal) tooth root sites. Markedly less favorable diagnostic test findings for the DetecTar device were found on proximal, as compared to non-proximal (buccal and lingual), root surface locations. The accuracy (diagnostic effectiveness) of DetecTar at non-proximal sites was excellent at 89.8%, but 22.7% lower at proximal sites (69.4%). Since the vast majority of deep periodontal pockets are located at interproximal dentition sites (Pihlstrom et al. 2005), where subgingival dental calculus detection is critical to assessing outcomes of periodontal mechanical instrumentation, the DetecTar differential reflectometry device appears to provide little definitive assistance to clinicians seeking help in their evaluation residual dental calculus in periodontal pockets after mechanical periodontal root instrumentation.

This study is limited by the use of plastic teeth instead of human teeth. Prior to the start of the study, a pilot test was conducted which confirmed that the DetecTar internal computer software did not identify the plastic surfaces of the typodont teeth as dental calculus. Repeated application of the device’s optical fiber tip to the plastic tooth surfaces failed to elicit an erroneous dental calculus recognition signal from the DetecTar instrument. Additionally, artificial dental calculus deposits, instead of authentic dental calculus, was scored by the DetecTar device on the plastic typodont teeth. Similarly, pilot testing prior to the onset of this study verified that the artificial dental calculus used in this study was recognized by the DetecTar instrument to a similar degree as human dental calculus deposits.

This study was conducted in an in vitro environment, rather than in human patients. Clearly, in vivo studies with the DetecTar differential reflectometry device are needed to better clarify its potential clinical utility, if any, in assisting detection of subgingival dental calculus at periodontal sites. The in vivo failure of negative DetecTar findings on approximately one out of six tooth root surfaces that still retained residual amounts of subgingival dental calculus after periodontal scaling and root planing (Kasaj et al. 2008), reinforces concerns as to the accuracy and reliability of the instrument in clinical settings.

CHAPTER 5

CONCLUSIONS

These study findings suggest marked limitations in the potential clinical utility of the DetecTar differential reflectometry device for detection of subgingival dental calculus. The device demonstrated markedly decreased in vitro accuracy on mesial and distal typodont tooth root surfaces, as compared to non-proximal tooth sites, and exhibited only a fair level of reproducibility in duplicate assessments.

The overall performance of the DetecTar differential reflectometry device appears to be inferior to similar assessments of typodont tooth root surfaces conducted by other investigators with more conventional tactile-based, manual instrumentation.

Based on these in vitro findings, routine clinical utilization of the DetecTar differential reflectometry device in dental practice is not recommended. Additional validation studies, conducted clinically in vivo, on the DetecTar differential reflectometry device are needed to further explore its potential application to periodontal evaluations.

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