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Evaluation of a New Microbiological 'Perio'-Diagnostic Chairside Test

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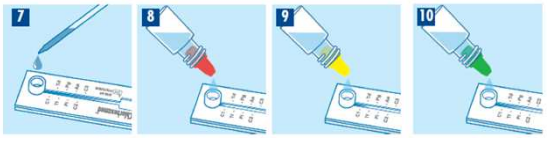
Objectives

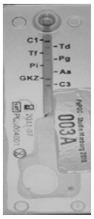
So far the assessment of periopathogenic bacteria requires more or less elaborate laboratory methods outside the dentist's office. As a consequence, the results are only available after 4-7 days. A newly developed bacterial test system for the detection of the five most relevant periodontal pathogens has the clear advantage of being used as a chairside test (CST) as it offers quick results within 30 minutes of the initial visit.
The aim of this clinical study was to determine the clinical sensitivity and specificity of the CST with respect to the overall clinical diagnosis and to a quantitative polymerase chain reaction (qPCR) method. Additionally, the clinical limit of detection was measured for all five pathogens.

Materials and methods

A total of 125 participants (59 female and 66 male) with an average age of 52.2±16.9 years were included in this study following a positive response from the University of Marburg's ethic committee (86/10). The study participants were divided into a test and control group according to pre-defined inclusion criteria. The test group consisted of 100 periodontally diseased participants and the control group included 25 periodontally healthy participants. Two samples of sulcus fluid from two teeth were pooled (two paper points). Each of the 125 samples was analysed at the point of care site by two different users with two CST kits. The CST assay was processed according to the manufacturer´s instructions and the results (positive signals for every pathogen and/or control) were independently interpreted by two examiners.

Results





Using the clinical diagnosis as a reference, the CST assay and the qPCR method reached a sensitivity of 87.82% and 94%, respectively. The specificity for both methods was 100%. The limits of detection for each periodontal pathogen of the CST in comparison to the qPCR reference method (LOD) were: $1.2x10^4$ for *Treponema denticola* (*T.d.*) and *Tannerella forsythensis* (*T.f.*); $2.5x10^4$ for *Porphyromonas gingivalis* (*P.g.*); $5.3x10^4$ for *Prevotella intermedia* (*P.i.*) and $5.8x10^4$ for *Aggregatibacter actinomycetemcomitans* (*A.a.*). When using the qPCR methodology as a reference method, the clinical sensitivities for each pathogen of the CST were as follows:

Species	LOD (calculated)	N pos. by *qPCR	N ≥ $LOD_{PerioPOC}$	N pos. by PerioPOC
Td	1.2×10^4	85	80 (94 %)	73 (91.3 %)
Tf	1.2×10^4	94	80 (85 %)	69 (86.3 %)
Pg	2.5×10^4	74	68 (91 %)	57 (83.8 %)
Pi	5.3×10^4	52	28 (53 %)	24 (85.7 %)
Aa	5.8×10^4	*31	15 (48 %)	15 (100 %)

***Not true prevalence of Aa, 16 samples were spiked**

The consistency between the chairside test and the so-called reference method can be classified as "good." The corrected sensitivity (i.e., the sensitivity within the maximum possible detection limit of approximately $1.2 – 5.8 \times 10^4$) can be classified as "excellent" with values between 84% and 100%. In a similar study for *A.a.* the sensitivity of 67% and the specificity of 100% were classified as "excellent."

Conclusion

This newly developed bacteria test can detect five typical periopathogenic bacteria. It provides an advantage over traditional microbiological assessment procedures (e.g. qPCR) as it can be used directly at the point of care (chairside) and provides immediate results. Moreover, it uses an RNA-based technique that only detects metabolically active bacteria, thus, partly explaining the differences when compared to the so-called reference method.

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